

EXHIBIT 36

1

1 UNITED STATES DISTRICT COURT

2 DISTRICT of MINNESOTA

3 - - - - -

4 In Re:

5 Bair Hugger Forced Air Warming

6 Products Liability Litigation

7

8 This Document Relates To:

9 All Actions MDL No. 15-2666 (JNE/FLM)

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13 DEPOSITION of THEODORE R. HOLFORD

14 VOLUME I, PAGES 1 - 386

15 JULY 18, 2017

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18 (The following is the deposition of THEODORE

19 R. HOLFORD, taken pursuant to Notice of Taking

20 Deposition, via videotape, at the Marriott Hartford

21 Downtown, 200 Columbus Boulevard, Hartford,

22 Connecticut, commencing at approximately 9:20 o'clock

23 a.m., July 18, 2017.)

24

25

1 APPEARANCES:

2 On Behalf of the Plaintiffs:

3 Michael A. Sachet and Jan M. Conlin
4 CIRESI CONLIN L.L.P.
5 225 South 6th Street, Suite 4600
6 Minneapolis, Minnesota 55402

7 On Behalf of Defendants:

8 Corey L. Gordon
9 BLACKWELL BURKE P.A.
10 432 South Seventh Street, Suite 2500
11 Minneapolis, Minnesota 55415

12 ALSO APPEARING:

13 Ronald M. Huber, Videotechnician

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1 P R O C E E D I N G S

2 (Witness sworn.)

3 THEODORE R. HOLFORD

4 called as a witness, being first duly sworn,
5 was examined and testified as follows:

07:45:25 6 ADVERSE EXAMINATION

09:20:04 7 BY MR. SACCHET:

09:20:07 8 Q. Good afternoon, Professor Holford. My name
09:20:09 9 is Michael Sacchet and I represent the plaintiffs in
09:20:12 10 this litigation.

09:20:13 11 Could you please state your full name for
09:20:15 12 the record.

09:20:15 13 A. Theodore Richard Holford.

09:20:18 14 Q. And Professor Holford, have you had your
09:20:21 15 deposition taken before?

09:20:21 16 A. Not on this.

09:20:23 17 Q. In the past?

09:20:24 18 A. Yes, I have.

09:20:25 19 Q. What was the subject matter of that
09:20:27 20 deposition?

09:20:30 21 A. Cigarette smoking.

09:20:32 22 Q. How long ago?

09:20:34 23 A. Ooh. It was probably eight years ago,
09:20:41 24 something like that, eight, 10 years ago.

09:20:44 25 Q. And were you called to offer opinion as to

09:20:48 1 biostatistics?

09:20:49 2 A. Yes.

09:20:50 3 Q. Epidemiology?

09:20:54 4 A. It was in regard to a statistical review
09:20:57 5 that I did of an epidemiology calculation paper -- or
09:21:01 6 chapter of a book, actually.

09:21:04 7 Q. What was the chapter of that book?

09:21:05 8 A. It was a chapter dealing with lung cancer
09:21:08 9 trends, and they were relating it to smoking.

09:21:13 10 Q. Okay. And were the studies that you relied
09:21:16 11 on in that chapter of the book observational studies?

09:21:20 12 A. Yes.

09:21:21 13 Q. What --

09:21:24 14 How many studies were there?

09:21:26 15 A. I don't recall. It was a -- quite a long --
09:21:30 16 quite a long time ago. I think some of it was
09:21:33 17 population data as I recall, but it's been -- been
09:21:35 18 quite a long time; I've forgotten the details of it.

09:21:39 19 Q. And who retained you to provide expert
09:21:42 20 testimony in that litigation?

09:21:47 21 A. It was the tobacco companies. They --
09:21:52 22 they -- I was -- I -- they de -- deposed me. They
09:21:59 23 subpoenaed me and wanted me to be a witness.

09:22:01 24 MR. GORDON: I -- I think he's not
09:22:05 25 understanding -- he's not tracking what you mean by

09:22:07 1 "retained."

09:22:08 2 MR. SACCHET: Yeah. I'll -- I'll clarify
09:22:09 3 the question.

09:22:10 4 MR. GORDON: Thank you.

09:22:11 5 Q. So the tobacco industry was examining
09:22:13 6 adversely or --

09:22:15 7 A. Yes.

09:22:15 8 Q. Okay. And who were you --

09:22:17 9 A. Well I -- yeah, I guess it was --

09:22:19 10 Yeah. They called me and it was because I
09:22:22 11 had been critical of one of the papers -- one of the
09:22:27 12 chapters at the time, and that's why I was deposed.

09:22:29 13 Q. What were you critical about?

09:22:31 14 A. Details on their analysis.

09:22:34 15 Q. And their analysis is that there was not
09:22:36 16 causation with respect to tobacco use and lung cancer?

09:22:40 17 A. No. No. It was --

09:22:41 18 The analysis had to do with looking at
09:22:44 19 trends, lung cancer trends --

09:22:46 20 Q. Okay.

09:22:47 21 A. -- and -- and disease trends, and that's an
09:22:50 22 area that's been of particular statistical interest.

09:22:54 23 Q. These were time trends?

09:22:56 24 A. Yes.

09:22:58 25 Q. Any other times in which you've offered

09:23:04 1 expert testimony, whether it be in a deposition or
09:23:06 2 through an expert report?

09:23:08 3 A. No.

09:23:08 4 Q. You're familiar with the rules of
09:23:14 5 deposition?

09:23:15 6 A. I think so.

09:23:16 7 Q. I'll just quickly review them so we're on
09:23:18 8 the same page.

09:23:19 9 As you know, I'll be asking you questions
09:23:21 10 and you'll be answering un -- them under oath. If you
09:23:23 11 don't understand a question, let me know and I'll do
09:23:26 12 my best to clarify. For purposes of the court
09:23:31 13 reporter, it's best if you allow me to finish my
09:23:34 14 question before you attempt to answer it so that we
09:23:36 15 have a clear record. And last and perhaps most
09:23:39 16 importantly, if you could answer all questions
09:23:42 17 verbally as opposed to nodding or shaking your head so
09:23:45 18 we have an opportunity to record your answer. Is that
09:23:47 19 agreeable?

09:23:48 20 A. Yes.

09:23:49 21 Q. In this litigation you've drafted a report;
09:23:53 22 correct, professor?

09:23:54 23 A. That's correct.

09:24:03 24 Q. We'll be marking this report as Exhibit 1.
09:24:06 25 I see you have one in front of you, but for the sake

11

09:24:09 1 of the exhibit, please determine whether it is a full
09:24:10 2 and accurate copy of the report you have submitted in
09:24:13 3 this case.

09:24:16 4 (Exhibit 1 was marked for
09:24:18 5 identification.)

09:24:18 6 MR. GORDON: This is just his report without
09:24:19 7 the CV?

09:24:20 8 MR. SACCHET: Yeah. I'll get there.

09:24:22 9 MR. SACCHET: And attached to your --

09:24:24 10 Well I'll let you look at it first.

09:24:33 11 (Exhibit 2 was marked for
12 identification.)

09:24:35 13 A. Yes, it appears to be complete.

09:24:37 14 Q. And you also attached your curriculum vitae
09:24:40 15 to your report; correct?

09:24:42 16 A. Yes.

09:24:42 17 Q. And is that an accurate copy of your CV from
09:24:44 18 what you can tell?

09:24:48 19 A. It appears to be so, yes.

09:24:49 20 MR. SACCHET: And as another housekeeping
09:25:01 21 matter, we are going to mark Dr. Samet's report as
09:25:07 22 Exhibit 3.

09:25:16 23 (Exhibit 3 was marked for
09:25:17 24 identification.)

09:25:17 25 BY MR. SACCHET:

09:25:18 1 Q. The report that you have filed in this case
09:25:21 2 responds to Dr. Samet's report; is that correct, Dr.
09:25:24 3 Holford?

09:25:24 4 A. Yes, that's correct.

09:25:26 5 Q. And that appears to be a full version of Dr.
09:25:30 6 Samet's report?

09:25:30 7 A. It appears to be, yes.

09:25:36 8 Q. Based on your curriculum vitae, I understand
09:25:40 9 that you have a B.A. in mathematics and chemistry; is
09:25:44 10 that correct?

09:25:44 11 A. That's correct.

09:25:44 12 Q. And you earned those degrees from Andrews
09:25:47 13 University?

09:25:47 14 A. Yes.

09:25:47 15 Q. Where is Andrews?

09:25:48 16 A. Berrian Springs, Michigan.

09:25:50 17 Q. Is that where you're from?

09:25:52 18 A. No.

09:25:53 19 Q. Why did you decide to go there?

09:25:57 20 A. Well my parents basically just made it clear
09:26:02 21 that that's where they wanted me to go.

09:26:05 22 Q. Okay. And you subsequently earned a Ph.D.
09:26:08 23 from Yale University in biometrics; correct?

09:26:10 24 A. That's correct.

09:26:11 25 Q. And biometrics is the application of

09:26:14 1 statistical methods to biological data?

09:26:16 2 A. Basically, yes.

09:26:19 3 Q. So in large part the focus is on statistics;
09:26:23 4 correct?

09:26:24 5 A. Yes.

09:26:24 6 Q. What is the relationship of biostatistics to
09:26:27 7 epidemiology?

09:26:29 8 A. Epidemiologists use biostatistics a lot in
09:26:35 9 their -- in their research, so there's often a
09:26:38 10 collaborative arrangement between epidemiologists
09:26:42 11 and -- and -- and statisticians.

09:26:44 12 Q. They are two separate fields though;
09:26:46 13 correct?

09:26:46 14 A. They are, yes.

09:26:47 15 Q. You do not have a degree in epidemiology;
09:26:49 16 correct?

09:26:49 17 A. No.

09:26:50 18 Q. You do not have clinical training in
09:26:54 19 epidemiology?

09:26:55 20 A. Most epidemiologists are not clinicians --
09:26:59 21 or many epidemiologists are not, so no, that's
09:27:03 22 correct.

09:27:03 23 Q. Some are; correct?

09:27:04 24 A. Some are.

09:27:05 25 Q. Dr. Samet is; correct?

09:27:06 1 A. Yes.

09:27:07 2 Q. You are not a medical doctor.

09:27:09 3 A. No, I am not.

09:27:10 4 Q. And you are not an anesthesiologist.

09:27:13 5 A. No.

09:27:14 6 Q. And you do not have experience in

09:27:16 7 arthroplasty; correct?

09:27:17 8 A. No.

09:27:19 9 Q. The majority of your professional career has

09:27:24 10 been at Yale University in a research and teaching

09:27:28 11 capacity; correct?

09:27:28 12 A. Yes, that's correct.

09:27:30 13 Q. I saw some examples on your curriculum vitae

09:27:34 14 in which you've gone elsewhere, I think Oxford

09:27:37 15 University and maybe a few other locations, to do

09:27:38 16 other work. Could you describe those -- those

09:27:44 17 opportunities briefly?

09:27:45 18 A. Yes. At Oxford I was on -- I had a

09:27:50 19 sabbatical year which I took at Oxford University.

09:27:53 20 Q. And what did you do during the sabbatical

09:27:56 21 year?

09:27:56 22 A. I -- I did research, I taught a class, and

09:28:00 23 I -- I basically worked on my research.

09:28:04 24 Q. Okay. With respect to the research that you

09:28:09 25 have published, you have focused on cancer; correct?

09:28:16 1 A. I've done a fair amount on cancer. It's not
09:28:20 2 the only thing I've worked on, but yes.

09:28:22 3 Q. Other topics that I noticed when I reviewed
09:28:24 4 some of your literature were articles on contraception
09:28:28 5 and pregnancy.

09:28:29 6 A. That was early on. It was -- it was more on
09:28:32 7 looking at the potential side effects of contraceptive
09:28:37 8 use.

09:28:38 9 Q. What would you say are the primary topics of
09:28:43 10 your research in addition to cancer, smoking,
09:28:47 11 contraception and pregnancy?

09:28:50 12 A. Air pollution is another thing that I've
09:28:53 13 worked on. Yeah, air pollution and childhood asthma.

09:29:03 14 Q. Okay. So I've read a couple of the articles
09:29:05 15 and what I can tell is that you have researched the
09:29:07 16 impact of particulates on respiratory disease;
09:29:11 17 correct?

09:29:11 18 A. Yes.

09:29:12 19 Q. Have you ever researched the impact of
09:29:14 20 particulates on other types of disease?

09:29:17 21 A. Not that I recall.

09:29:21 22 Q. So it's limited to the impact on respiratory
09:29:24 23 diseases.

09:29:25 24 A. Yes, particularly childhood -- childhood
09:29:28 25 asthma.

09:29:32 1 Q. Any other topics of focus?

09:29:36 2 A. Oh, I've occasionally done things related to
09:29:45 3 in -- infectious diseases. My dissertation research
09:29:50 4 was on schistosomiasis and statistical modeling for
09:29:56 5 that. I've done work with a clinical trial on spinal
09:30:01 6 cord injuries, the treatment for spinal cord injury.

09:30:06 7 Q. Okay.

09:30:12 8 A. Lots of work in cancer of course,
09:30:14 9 various -- various aspects of it. Currently, I'm
09:30:17 10 doing a lot of work on population models for cancer,
09:30:22 11 mostly lung cancer, but --

09:30:24 12 Q. Okay.

09:30:25 13 A. -- yeah, it's related.

09:30:26 14 Q. You have not researched computational fluid
09:30:29 15 dynamics; correct?

09:30:31 16 A. No.

09:30:31 17 Q. You have not performed research on operating
09:30:33 18 room airflow; correct?

09:30:35 19 A. On operating --

09:30:37 20 On what?

09:30:38 21 Q. Room airflow.

09:30:39 22 A. No.

09:30:39 23 Q. How about filtration of operating rooms?

09:30:42 24 A. No.

09:30:43 25 Q. What about filtration of medical devices?

09:30:46 1 A. No.

09:30:47 2 Q. What about anesthesia?

09:30:49 3 A. No.

09:30:50 4 Q. Microbiology?

09:30:52 5 A. No.

09:30:53 6 Q. Orthopedics?

09:30:55 7 A. No.

09:30:56 8 Q. So I assume that means no for deep joint

09:31:00 9 infection.

09:31:00 10 A. Yes.

09:31:01 11 Q. Are you offering testimony as to any of

09:31:03 12 those subject matters?

09:31:06 13 A. I'm offering testimony on statistical

09:31:10 14 aspects that relate to the -- the Bair Hugger. I

09:31:16 15 don't know if you think that's related or not.

09:31:18 16 Q. But as to the core topic of those subject

09:31:22 17 matters --

09:31:23 18 A. Those subjects, no.

09:31:24 19 Q. -- you are not opining --

09:31:25 20 A. No, I am not.

09:31:26 21 Q. -- about them discretely; correct?

09:31:28 22 A. That's correct.

09:31:28 23 Q. So you are not responding to the reports of

09:31:30 24 Dr. Said Elghobashi, for example, --

09:31:34 25 A. No.

09:31:35 1 Q. -- which is a report on computational fluid
09:31:38 2 dynamics.

09:31:38 3 A. Yeah. No, I am not.

09:31:39 4 Q. And you are not responding to Dr. Jarvis's
09:31:43 5 report from a microbiology standpoint; correct?

09:31:44 6 A. Not from a microbiology standpoint.

09:31:47 7 Q. Is your testimony limited to the McGovern
09:31:49 8 study?

09:31:49 9 A. Primarily, yes.

09:31:51 10 Q. What do you mean by "primarily?"

09:31:53 11 A. Well that -- that was the focus of what I
09:31:55 12 was looking at, was the McGovern study.

09:31:57 13 Q. Your report says that "This report is a
09:31:59 14 review of the observational study of risk for deep
09:32:02 15 joint infection following the use of Bair Hugger
09:32:04 16 warming device during hip and knee replacement
09:32:07 17 surgery...;" correct?

09:32:09 18 A. Yes.

09:32:10 19 MR. GORDON: To clarify, subsequent to his
09:32:12 20 report and -- and in light of Dr. Samet's reliance on
09:32:17 21 the newly published Augustine paper, we've asked him
09:32:20 22 to take a look at that.

09:32:21 23 Q. To the extent that Dr. Samet's causal
09:32:25 24 inference depends on factors outside of the McGovern
09:32:28 25 study, you do not have an expertise to opine on that

09:32:31 1 subject matter; correct?

09:32:34 2 A. Yes.

09:32:39 3 Q. To the extent that Dr. Samet's report
09:32:44 4 includes his experience as a medical doctor, you do
09:32:46 5 not have expertise to respond to those opinions;
09:32:51 6 correct?

09:32:51 7 A. Not the particular ones that related to the
09:32:54 8 medical opinions, yes.

09:32:56 9 Q. To the extent that Dr. Samet's report relies
09:32:58 10 on his training in anesthesiology, you do not have
09:33:04 11 expertise to respond those conclusions; correct?

09:33:04 12 A. That's correct.

09:33:06 13 Q. To the extent that Dr. Samet's opinions
09:33:12 14 hinge on his experience as a clinical epidemiologist,
09:33:15 15 you do not have experience to respond to those
09:33:17 16 opinions; correct?

09:33:19 17 A. I have not been a clinical epidemiologist,
09:33:28 18 no. I have worked -- worked with a lot of others that
09:33:28 19 have done, you know, clinical epidemiology work so
09:33:30 20 I've been involved with people doing that kind of
09:33:33 21 work, but primarily from a statistical perspective.

09:33:37 22 Q. So you don't have expertise to respond to
09:33:38 23 the clinical side of epidemiology; correct?

09:33:40 24 A. Correct.

09:33:42 25 Q. So you are not responding to Dr. Samet's

09:33:45 1 opinions to the extent that they rely on a clinical
09:33:49 2 perspective of epidemiology; correct?

09:33:50 3 A. Not the clinical perspective, that's right.

09:33:53 4 Q. To the extent Dr. Samet's opinions rely on
09:33:57 5 his experience with filtration, you are not responding
09:34:00 6 to those opinions; are you?

09:34:02 7 A. No.

09:34:04 8 Q. And to the extent that Dr. Samet relies on
09:34:09 9 his experience in particulate matter, you're not
09:34:15 10 responding to those opinions; are you?

09:34:18 11 A. No.

09:34:30 12 Q. You nonetheless opine, however, that
09:34:33 13 particles are simply an intermediate proxy for deep
09:34:38 14 joint infection; correct?

09:34:42 15 A. I'm sorry, could you repeat that?

09:34:44 16 Q. Your report states that particles are at
09:34:46 17 most an intermediate outcome that has not been shown
09:34:49 18 to directly relate to the outcome of interest, deep
09:34:51 19 joint infection; correct?

09:34:53 20 A. Yes.

09:34:54 21 Q. If you do not have the expertise that Dr.
09:34:58 22 Samet has in airborne particulate matter, on what
09:35:00 23 basis are you making that conclusion?

09:35:02 24 MR. GORDON: Object to the form of the
09:35:04 25 question.

21

09:35:06 1 A. I'm sorry, could you repeat the question?

09:35:08 2 Q. To the extent that you have concluded that
09:35:10 3 particles are at most an intermediate outcome that has
09:35:13 4 not been shown to relate to the outcome of interest,
09:35:16 5 deep joint infection, on what basis are you making
09:35:18 6 that conclusion?

09:35:20 7 A. I'm basing that on the -- on the -- some of
09:35:26 8 the manuscripts related -- related to that and some of
09:35:30 9 the other testimony and things that I've related to
09:35:32 10 that or related to the pub -- in terms of the Bair
09:35:35 11 Hugger.

09:35:35 12 Q. Which manuscripts?

09:35:45 13 A. I'm -- let's see. I've --

09:35:52 14 There's some of the work that the
09:36:01 15 Albright -- Albrecht, is that -- the person that works
09:36:05 16 with Augustine, and some of -- some of that work where
09:36:13 17 they were -- where they were trying to look at the --
09:36:20 18 the output from the device and look at the infection,
09:36:26 19 look -- looking for organisms deposited on agar plates
09:36:30 20 from -- from that, it was one of those papers.
09:36:33 21 I've -- I've forgotten exactly which -- which the
09:36:36 22 author was, but I re -- remember that recollection, so
09:36:39 23 that's the basis of that.

09:36:40 24 Q. And that's your only basis?

09:36:42 25 A. That's primarily my only basis, yes.

09:36:44 1 Q. You know that Mr. Albrecht is not a
09:36:49 2 microbiologist; right?

09:36:49 3 A. Yes.

09:36:50 4 Q. You have not reviewed any published studies
09:36:53 5 regarding the link between particles and bacteria and
09:36:56 6 deep joint infection?

09:36:57 7 A. No, that's not been -- been my primary
09:37:01 8 focus.

09:37:01 9 Q. So with respect to the conclusion that
09:37:03 10 particles are at most an intermediate outcome that has
09:37:06 11 not been shown to directly relate to the outcome of
09:37:09 12 interest, deep joint infection, you are solely relying
09:37:11 13 on Albrecht's manuscript.

09:37:13 14 A. His manuscript and his testimony where he
09:37:16 15 was describing how he was trying to deposit organisms
09:37:22 16 onto agar plates and -- and that kind of stuff. He
09:37:26 17 was --

09:37:26 18 That was not successful, as I recall.

09:37:33 19 Q. And you're referring to his deposition
09:37:35 20 transcript; correct?

09:37:36 21 A. Yes.

09:37:42 22 Q. Have you listed everything that you have
09:37:43 23 relied on on page 14 of your report, which outlines 19
09:37:49 24 different sources?

09:37:57 25 A. I think so. That's the -- that's basically

09:37:57 1 what I relied on in writing this, yes.

09:38:00 2 Q. Have you reviewed anything since you filed
09:38:03 3 your report until today in addition to those sources?

09:38:11 4 A. I reviewed the recent paper by Augustine
09:38:20 5 and, let's see, what else? That's most of what I --
09:38:27 6 what I have -- have re -- reviewed. I -- I saw some
09:38:38 7 of -- a small piece of Augustine's dep -- deposition,
09:38:44 8 and that's -- that's about it.

09:38:46 9 Q. Okay. I'm going to circle back to
09:38:49 10 Albrecht's deposition testimony with respect to the
09:38:52 11 testing that he did on particles and bacteria.

09:39:04 12 (Exhibit 4 was marked for
09:39:09 13 identification.)

09:39:09 14 BY MR. SACCHET:

09:39:10 15 Q. This is an excerpt of Mr. Albrecht's
09:39:13 16 deposition; correct?

09:39:17 17 A. Yes.

09:39:19 18 Q. And if you could turn to page seven in the
09:39:25 19 bottom right-hand corner, or internal page 23 in the
09:39:32 20 top right-hand corner --

09:39:34 21 MR. GORDON: Did you mark this?

09:39:36 22 THE REPORTER: Yes.

09:39:37 23 MR. SACCHET: I did.

09:39:40 24 THE REPORTER: That's four.

09:39:45 25 Q. -- and you'll see line 23 of page 23 says,

09:39:49 1 "...Exhibit 1 is a report for -- from certain work --
09:39:53 2 research activities that were done at the Regina
09:39:56 3 Surgery Center..." Do you see that, --

09:39:58 4 A. Yes.

09:39:58 5 Q. -- Professor Holford?

09:40:00 6 A. Uh-huh.

09:40:00 7 Q. Is this one of the exhibits that you rely on
09:40:05 8 with respect to Mr. Albrecht's testimony regarding
09:40:09 9 bacteria?

09:40:23 10 MR. GORDON: Do you have that exhibit?

09:40:24 11 MR. SACCHET: I do.

09:40:27 12 A. I -- I think this is -- this is -- this is
09:40:30 13 the one, yes.

09:40:31 14 Q. Did you rely on the deposition testimony or
09:40:34 15 the exhibits to the deposition when you concluded that
09:40:37 16 particles are at most an indeterminate outcome?

09:40:40 17 MR. GORDON: Object to the form of the
09:40:42 18 question.

09:40:44 19 A. I was -- I was relying primarily on the --
09:40:47 20 on the deposition.

09:40:50 21 Q. Have you seen the Exhibit 1 that was marked
09:40:54 22 at this deposition?

09:40:57 23 A. I -- I don't recall.

09:41:10 24 (Exhibit 5 was marked for
09:41:12 25 identification.)

09:41:12 1 BY MR. SACCHET:

09:41:15 2 Q. Does this document refresh your recollection
09:41:18 3 as to whether you have reviewed Exhibit 1 of the
09:41:21 4 Albrecht deposition?

09:41:27 5 A. No. I did not see this document.

09:41:29 6 Q. You've never seen the document before.

09:41:31 7 A. No.

09:41:31 8 Q. So you only relied on the deposition
09:41:34 9 transcript in determining that particles are at most
09:41:37 10 an indeterminate outcome of deep joint infection.

09:41:41 11 MR. GORDON: Object to the form of the
09:41:42 12 question, assumes facts not in evidence.

09:41:52 13 A. I think what I'm saying is that this -- this
09:41:54 14 document is not -- was -- was not what I had
09:42:00 15 considered.

09:42:00 16 Q. Did you review any of the exhibits that were
09:42:04 17 marked at the Albrecht deposition with respect to the
09:42:08 18 testimony regarding testimony of particulates versus
09:42:12 19 bacteria?

09:42:12 20 A. I didn't review the exhibits, no.

09:42:15 21 Q. Okay. Let's go back to the transcripts
09:42:17 22 then. And I believe your conclusion about particles
09:42:28 23 being related to bacteria can be found on page 19 in
09:42:33 24 the bottom right-hand corner, or page 73, which is the
09:42:37 25 internal page.

09:42:43 1 MR. GORDON: What page?

09:42:44 2 MR. SACCHET: Nineteen TSG, internal 73.

09:42:47 3 MR. GORDON: Oh, I see. All right.

09:42:52 4 Q. And line 16 states, "Okay. Did -- so you --

09:42:57 5 you found that there were particles of various sizes,

09:43:00 6 various counts coming out of the Bair Hugger?"

09:43:03 7 Response: "Yes, we did.

09:43:05 8 "Question: But you really didn't find much

09:43:07 9 in the way of bacteria coming out?"

09:43:08 10 Response: "We did not."

09:43:10 11 A. Yes.

09:43:12 12 Q. Did you review the other sections of this

09:43:15 13 deposition transcript aside from that conclusion?

09:43:19 14 A. That's most of what I -- what I noticed in

09:43:24 15 that report, yes.

09:43:25 16 Q. Okay. If I could draw your attention to the

09:43:34 17 Exhibit 5, which is the report that is cited in this

09:43:38 18 deposition transcript, the last page, page 12, notes

09:43:44 19 that, in the first bullet point, "...testing done in

09:43:50 20 our lab rated the 505 intake filter at roughly 94

09:43:56 21 percent;" correct?

09:44:00 22 A. Yes, that's what it says.

09:44:03 23 Q. Do you have any reason to doubt that the

09:44:05 24 testing that was done with respect to Mr. Albrecht's

09:44:08 25 testimony in this transcript involved a device

09:44:12 1 different than the 505?

09:44:14 2 MR. GORDON: Object to the form of the
09:44:15 3 question, lack of foundation.

09:44:17 4 A. I have no idea what they were using. I
09:44:20 5 mean --

09:44:20 6 Yeah, I don't -- I don't know.

09:44:23 7 Q. This exhibit makes clear that testing was
09:44:31 8 done on the 505; correct?

09:44:33 9 A. Yes.

09:44:34 10 Q. Are you aware that the model 505 uses a
09:44:37 11 different filter than the Bair Hugger model 750 and
09:44:41 12 775?

09:44:42 13 A. No. I -- I'm not familiar with -- with
09:44:45 14 which filters are used on them.

09:44:47 15 Q. You cited the Reed article in your reference
09:44:50 16 list; correct?

09:44:51 17 A. Yes.

09:44:52 18 Q. Did you review that article?

09:44:53 19 A. I did look at that article, yes.

09:45:04 20 Q. So you reviewed the article but you're not
09:45:06 21 aware that there are two different filter efficiencies
09:45:09 22 for the model 505 versus the model 750.

09:45:12 23 MR. GORDON: Object to the form of the
09:45:13 24 question.

09:45:14 25 A. I was not reviewing the particular filters.

09:45:27 1 (Exhibit 6 was marked for
09:45:29 2 identification.)
09:45:29 3 BY MR. SACCHET:
09:45:31 4 Q. If you could turn your attention to the
09:45:37 5 column in the right-hand side on page one, the first
09:45:41 6 full sentence starts with "Prior research..." Do you
09:45:44 7 see that, Dr. Holford? On the first page, right-hand
09:45:48 8 column.
09:45:50 9 Text, not abstract.
09:45:56 10 A. "Prior research," is that what you said?
09:45:58 11 Q. Yes.
09:45:59 12 A. Yeah. Okay.
09:45:59 13 Q. "Prior research has rated the intake
09:46:03 14 filtration efficiency of legacy FAW devices (Bair
09:46:06 15 Hugger 505, Arizant Healthcare) at 93.8 percent for an
09:46:12 16 'older' filter model in clinical use (200708C) and
09:46:20 17 61.3 percent for a 'newer' filter model (200708D)
09:46:29 18 scheduled to replace the older filter in clinical
09:46:31 19 use." Do you see that?
09:46:32 20 A. Yes.
09:46:33 21 Q. Does that make clear that there are two
09:46:35 22 different filtration capacities?
09:46:36 23 A. Yes, it does.
09:46:37 24 Q. And the older filter that we're talking
09:46:40 25 about has been denominated as the Bair Hugger 505;

09:46:42 1 correct?

09:46:43 2 A. Yes.

09:46:44 3 Q. And below that, do you see the reference to
09:46:46 4 Bair Hugger 750 in the next paragraph?

09:46:49 5 A. Yes.

09:46:50 6 Q. Are you now aware that there are two
09:46:53 7 different filtration efficiencies?

09:46:54 8 A. Yes.

09:47:05 9 Q. If we could now turn back to the deposition
09:47:08 10 transcript, which has been marked as Exhibit 4, and if
09:47:15 11 you could turn to page 40, internal page 40, and line
09:47:30 12 nine states, "We were assessing filtration efficiency
09:47:34 13 and that dealt with particles on the in and out
09:47:37 14 stream, because it's very important in case there are
09:47:39 15 resident airborne microbes that could be sucked in and
09:47:42 16 delivered through." Do you see that?

09:47:44 17 A. Yes.

09:47:44 18 Q. Based on that testimony and the documents we
09:47:48 19 have reviewed, is it clear to you that Mr. Albrecht
09:47:52 20 was conducting testing on the filter of the model 505?

09:47:55 21 MR. GORDON: Object to the form of the
09:47:56 22 question, lacks foundation.

09:48:02 23 A. I'm not -- I guess I'm not really under --
09:48:07 24 understanding if he's testing the filter or if he's
09:48:10 25 testing -- you know, filter per se, because as I -- as

09:48:14 1 I understand it, there's a whole mechanism that's --
09:48:16 2 that's involved here. It's not just the filter.

09:48:19 3 Q. Okay. Let's look at what's been marked as
09:48:23 4 Exhibit 5, the report.

09:48:36 5 A. Okay.

09:48:37 6 Q. Do you see point four?

09:48:39 7 A. Yeah.

09:48:39 8 Q. Says, "Impaction: Impaction sampling will
09:48:44 9 be performed on the air stream in the distal region of
09:48:47 10 the hose on a non-specific growth media."

09:48:51 11 A. Okay.

09:48:51 12 Q. Are you aware that in order to test whether
09:48:55 13 anything would come out of the hose, it would first
09:48:57 14 need to travel through the filter of the device?

09:49:00 15 A. Yes.

09:49:00 16 MR. GORDON: Object to the form of the
09:49:02 17 question, lack of foundation.

09:49:03 18 Q. You are aware of that.

09:49:04 19 A. It would have --

09:49:05 20 It would apparently go through -- through
09:49:07 21 the filter, yes.

09:49:08 22 Q. So with respect to this testing, the model
09:49:11 23 505 was tested to determine whether particles moved
09:49:15 24 through the filter and out of the distal hose;
09:49:19 25 correct?

09:49:19 1 MR. GORDON: Same object -- same objection.

09:49:23 2 A. It would be doing that, but I've already
09:49:26 3 said that this -- this particular document was not
09:49:31 4 something that I -- I was reviewing.

09:49:33 5 Q. Well this is a document that's referenced in
09:49:36 6 the deposition of the testing that was done with
09:49:38 7 respect to what you're relying on; correct?

09:49:40 8 MR. GORDON: Object to the form of the
09:49:41 9 question, and also misconstrues the evidence.

09:49:46 10 A. What I -- what I think I've -- what I said
09:49:49 11 was -- is I looked at the deposition, I was -- I did
09:49:53 12 not refer to the -- directly to the -- to all -- to
09:49:59 13 all of the exhibits in it.

09:50:00 14 Q. So now that we're reviewing the exhibit,
09:50:04 15 that is a document -- the testing that was performed
09:50:06 16 by Mr. Albrecht, does that enlighten your viewpoint?

09:50:09 17 MR. GORDON: Well object to the form of the
09:50:10 18 question. Counsel, you've shown him one exhibit.
09:50:13 19 There were multiple exhibits marked in the
09:50:15 20 Augus -- at the Albrecht deposition.

09:50:17 21 Q. We can go back to the line in the exhibit
09:50:20 22 which we reviewed just a moment ago on page --
09:50:23 23 internal page 23 that says, "...Exhibit 1 is a report
09:50:29 24 for -- from certain work -- research activities that
09:50:32 25 were done at the Regina Surgery Center..." Do you

09:50:36 1 have any reason to doubt --

09:50:38 2 MR. GORDON: But that -- that's true,
09:50:39 3 counsel, but you're -- you've jumped ahead about 50
09:50:42 4 pages in the deposition, and I -- I was there, I took
09:50:45 5 it. There were other exhibits marked. We were not
09:50:47 6 talking exclusively about Exhibit 1, and I think
09:50:51 7 that's really unfair.

09:50:53 8 MR. SACCHET: There's one other exhibit I
09:50:55 9 can maintain that regards the testimony that Mr.
09:50:57 10 Albrecht gave in that deposition, and that has been
09:51:00 11 marked as Albrecht Exhibit 3. Is that what you're
09:51:01 12 referring to, Mr. Gordon?

09:51:01 13 MR. GORDON: I don't know. You'd have to
09:51:03 14 show it to me. But there was -- it wasn't just the
09:51:05 15 Regina testing; there were three different tests.

09:51:08 16 Q. Okay. So let's just look at the deposition
09:51:10 17 testimony if you're unwilling to conclude that
09:51:13 18 Exhibit 1 is -- is the foundation for the testimony
09:51:15 19 that Mr. Albrecht provided.

09:51:17 20 On line 36 of the deposition transcript --
09:51:25 21 or excuse me, page 36, if you could turn to that, Dr.
09:51:37 22 Holford, line five states:

09:51:39 23 "So you were looking for particles coming
09:51:42 24 out, that were being blown out of the Bair Hugger --
09:51:44 25 "Uh-huh."

09:51:45 1 Do you see that?

09:51:46 2 A. Yes.

09:51:46 3 Q. And the subsequent lines say:

09:51:49 4 "Question: -- that was the particle

09:51:51 5 counting?

09:51:52 6 "But with the impaction counting you were

09:51:54 7 looking to see if there were any actual bacteria that

09:51:57 8 were being blown out of the Bair Hugger?

09:52:00 9 "Correct."

09:52:00 10 A. Yes.

09:52:02 11 Q. Does that provide an example of the

09:52:07 12 testimony that you relied on in determining that Mr.

09:52:10 13 Albrecht's testing involved whether Bair Hugger --

09:52:14 14 whether bacteria came out of the Bair Hugger?

09:52:21 15 A. Are you asking for --

09:52:23 16 I don't understand the -- the question. Are

09:52:25 17 you asking was he looking at any -- whether or not any

09:52:30 18 particles were coming out of the Bair Hugger --

09:52:34 19 Q. Does this --

09:52:35 20 A. -- or are you asking whether there were

09:52:37 21 bacteria that were coming out of the Bair Hugger?

09:52:40 22 Q. Was Mr. Albrecht trying to determine that

09:52:42 23 bacteria were being blown out of the Bair Hugger?

09:52:44 24 A. He was trying to do that, yes.

09:52:46 25 Q. Okay. Do you know how he was trying to

09:52:48 1 sample whether bacteria were coming out of the Bair

09:52:51 2 Hugger?

09:52:53 3 A. As I've said, this is not really my area,

09:52:59 4 but I -- my understanding was the -- that the kinds of

09:53:02 5 things that he was doing is blowing it on agar plates

09:53:05 6 and things like that.

09:53:06 7 Q. Do you know what he was blowing it out of?

09:53:08 8 A. The Bair Hugger, this -- this device.

09:53:11 9 Q. Do you know whether he was blowing it out of

09:53:13 10 the hose or out of the blanket?

09:53:16 11 A. I -- I --

09:53:18 12 It's been a while since I read that. I

09:53:22 13 think it was out of the -- out of the blanket, but I

09:53:24 14 may be -- I may be --

09:53:27 15 I don't recall -- really recall.

09:53:29 16 Q. Do you know whether bacteria was tested at

09:53:32 17 the surgical site?

09:53:36 18 A. At --

09:53:36 19 During the surgery?

09:53:37 20 Q. Was bacteria being collected at the surgical

09:53:40 21 site?

09:53:41 22 MR. GORDON: At what point?

09:53:43 23 THE WITNESS: At what point?

09:53:43 24 MR. SACCHET: During the testing.

09:53:44 25 MR. GORDON: Which -- which testing?

09:53:46 1 MR. SACCHET: During the testing that Mr.
09:53:47 2 Albrecht discusses in his deposition transcript that
09:53:50 3 you relied on in opining that particles are at best an
09:53:54 4 indeterminate outcome of bacteria.

09:53:59 5 A. I'm opining that -- you're looking --
09:54:01 6 If you're just looking at particles, that's
09:54:03 7 not looking at whether bacteria are on those
09:54:06 8 particles.

09:54:07 9 Q. And you have stated that --
09:54:09 10 A. My understanding was what he was looking at
09:54:11 11 is whether or not there were particles.

09:54:14 12 Q. Okay. And you have stated that the
09:54:16 13 foundation for your testimony that particles are at
09:54:18 14 most an indeterminate outcome for bacteria is the
09:54:21 15 Albrecht testing; correct?

09:54:23 16 A. If -- if you're not looking -- if you're not
09:54:26 17 specifically looking at what those particles are, then
09:54:32 18 that's indirect evidence --

09:54:36 19 Q. Are you --
09:54:36 20 A. -- is what I'm -- what I'm saying.

09:54:38 21 Q. Okay. Are you --
09:54:39 22 A. Is that --

09:54:40 23 Q. Are you aware that Mr. Albrecht was only
09:54:42 24 testing whether bacteria could be cultured from the
09:54:45 25 air that came through the hose?

09:54:47 1 MR. GORDON: Object to the form of the
09:54:48 2 question.

09:54:50 3 A. I think he was trying to, yeah, culture
09:54:53 4 that -- what was coming out of the hose, yes.

09:54:58 5 Q. Mr. Albrecht did not conduct testing to
09:55:00 6 determine whether disruption in airflow currents in
09:55:05 7 the operating room caused bacteria to enter the
09:55:08 8 surgical site; correct?

09:55:09 9 MR. GORDON: Object to the form of the
09:55:10 10 question, assumes facts not in evidence, lack of
09:55:13 11 foundation.

09:55:16 12 A. Yeah. I'm not under -- really understanding
09:55:18 13 what your question is. I --

09:55:20 14 Q. You reviewed Mr. Albrecht's transcript; --

09:55:22 15 A. Yes.

09:55:22 16 Q. -- correct?

09:55:23 17 Did you see any mention in the transcript as
09:55:26 18 to whether Mr. Albrecht did any testing beyond simply
09:55:30 19 sampling bacteria out of the hose?

09:55:35 20 A. Do you mean taking a swab out of -- of -- in
09:55:39 21 the hose itself, --

09:55:40 22 Q. No.

09:55:40 23 A. -- is that what you're saying?

09:55:43 24 Q. I'm saying the only testing that Mr.
09:55:45 25 Albrecht did was collecting bacteria in an agar plate

09:55:48 1 from air that came out of the hose of the device.

09:55:50 2 A. He was trying to do that, yes.

09:55:52 3 Q. And that's the only testing that he did.

09:55:54 4 A. No. He was doing other -- other testing. I
09:55:58 5 mean there was more to that ex -- those experiences he
09:56:02 6 was doing. He was trying a number of different
09:56:03 7 things.

09:56:03 8 Q. In terms of bacterial collection, did he do
09:56:06 9 anything else?

09:56:08 10 A. He also swabbed, I think, the -- the -- the
09:56:12 11 tube.

09:56:12 12 Q. Did he do anything else with respect to
09:56:14 13 either swabbing the interior of the tube or collecting
09:56:16 14 bacteria in an agar plate from the air that came
09:56:19 15 directly out of the hose?

09:56:19 16 A. I don't recall. I don't recall whether he
09:56:23 17 did or not.

09:56:24 18 Q. So you don't recall whether Mr. Albrecht did
09:56:26 19 any testing to see whether the Bair Hugger created
09:56:30 20 convection currents that caused bacteria in the
09:56:33 21 operating room to go to the surgical site.

09:56:37 22 A. I don't recall seeing any direct evidence
09:56:38 23 of -- of that.

09:56:39 24 Q. And you're aware that Dr. Samet has opined
09:56:43 25 that there are two mechanisms of infection; correct?

09:56:47 1 A. Yes.

09:56:47 2 Q. One mechanism is bacteria coming directly
09:56:50 3 from the Bair Hugger device itself; correct?

09:56:54 4 A. Yes.

09:56:54 5 Q. And the other mechanism is from the air --
09:56:57 6 from the airflow being generated from the Bair
09:57:00 7 Hugger --

09:57:00 8 A. Yes.

09:57:00 9 Q. -- causing bacteria to enter the surgical
09:57:02 10 site; correct?

09:57:03 11 A. Yes.

09:57:04 12 Q. So you're not aware of whether Mr. Albrecht
09:57:06 13 did any testing that goes to the second causal
09:57:09 14 mechanism; correct?

09:57:11 15 A. Well I mean I think the -- the mechanism
09:57:14 16 we -- we've talked about where he's looking at the --
09:57:17 17 at what came out -- came out of the -- out of the
09:57:20 18 device, my assumption is that he was interested in
09:57:24 19 that because that -- that would then en -- enter
09:57:27 20 the -- the -- the air around the -- where -- where the
09:57:33 21 surgery was being conducted, and that that would be a
09:57:36 22 mode of -- for the -- for the second mode of -- of
09:57:40 23 infection that Samet is talking about.

09:57:42 24 Q. Dr. Samet does not conflate the first
09:57:44 25 mechanism with the second mechanism; correct?

09:57:46 1 A. Yes.

09:57:47 2 Q. So there is an entirely separate mechanism
09:57:49 3 which involves air being generated in the operating
09:57:52 4 room --

09:57:52 5 A. Yes.

09:57:53 6 Q. -- that causes bacteria to land on the
09:57:54 7 surgical site.

09:57:55 8 A. Right.

09:57:56 9 Q. Mr. Albrecht's test -- Mr. Albrecht's
09:57:59 10 testing was about air coming out of the hose into an
09:58:02 11 agar plate; correct?

09:58:04 12 A. Yes.

09:58:04 13 MR. GORDON: Objection, lack of foundation.

09:58:05 14 Q. That does not directly involve whether
09:58:07 15 airflow created currents that caused bacteria to enter
09:58:09 16 the surgical site.

09:58:12 17 A. It might, but it -- but -- but --

09:58:18 18 Yeah. I mean it's not -- it's not directly
09:58:21 19 testing it while the operation is -- is being
09:58:24 20 conducted. He's -- he's trying to get indirect
09:58:27 21 evidence of that -- that -- that -- that mechanism of
09:58:31 22 where the infection could have been caused.

09:58:33 23 Q. So to the extent that you have concluded
09:58:35 24 based on Mr. Albrecht's testimony that particles are
09:58:39 25 at most an indeterminate outcome -- intermediate

09:58:41 1 outcome of deep joint infections, it relates solely to
09:58:45 2 the first causal mechanism that Dr. Samet described in
09:58:49 3 his report.

09:58:49 4 MR. GORDON: Object to the form of the
09:58:50 5 question, misstates the testimony.

09:58:54 6 A. The -- the two mechanisms --

09:58:57 7 I'm sorry, what -- what did you call the
09:58:58 8 first one?

09:58:58 9 Q. The first mechanism of infection is bacteria
09:59:01 10 being blown directly out of the Bair Hugger onto the
09:59:04 11 surgical site.

09:59:08 12 A. Yes.

09:59:08 13 Q. The second mechanism of infection that Dr.
09:59:12 14 Samet describes is the Bair Hugger creating convection
09:59:15 15 currents in the operating room airflow --

09:59:17 16 A. Right. Okay.

09:59:18 17 Q. -- that cause bacteria from anywhere in the
09:59:20 18 operating room, not just the Bair Hugger device, --

09:59:22 19 A. Right.

09:59:23 20 Q. -- to enter the surgical field.

09:59:25 21 A. Yes.

09:59:25 22 Q. Mr. Albrecht's testing did not involve
09:59:28 23 mechanism two.

09:59:29 24 A. That's correct.

09:59:30 25 Q. To the extent that you have opined that

09:59:32 1 particles are at best an indeterminate outcome of deep
09:59:37 2 joint infection, you are relying on Mr. Albrecht's
09:59:40 3 testimony; correct?

09:59:40 4 A. In part, yes.

09:59:42 5 Q. You told me in full. Is there something
09:59:45 6 else now that you're relying on to make that
09:59:47 7 conclusion?

09:59:48 8 A. Well the -- what he --

09:59:51 9 As I understand it, what he was looking at
09:59:53 10 was particles and without distinguishing exactly what
09:59:59 11 those particles were, so what I'm saying, he looked --

10:00:07 12 You know, there are particles there, that's
10:00:09 13 part of what he shows; some of them may come directly
10:00:13 14 from the hose, some of them maybe have been -- involve
10:00:17 15 the second -- second mechanism where it disturbed the
10:00:20 16 air around it and has particles from that. What I'm
10:00:24 17 opining on is that the -- directly measuring bacteria
10:00:31 18 or infectious agents on those particles, that's --
10:00:37 19 that's what I was referring to.

10:00:39 20 Q. But you would agree that Mr. Albrecht's
10:00:43 21 testing did not directly relate to causal mechanism
10:00:46 22 two. You've already said that.

10:00:50 23 MR. GORDON: Object.

10:00:50 24 A. Okay. Yes.

10:00:51 25 Q. And so your conclusion, which are that

10:00:55 1 particles are an indeterminate outcome of deep joint
10:00:57 2 infection, relies on Mr. Albrecht's conclusions as to
10:01:01 3 causal mechanism number one.

10:01:06 4 A. In -- in part, yes. But the --

10:01:10 5 To say that what's on the particles, I mean
10:01:14 6 that -- that -- I'm -- I'm making that -- that -- that
10:01:19 7 claim generally. It's more than just looking at
10:01:23 8 whether or not the particles have been dispersed, it's
10:01:26 9 looking at what -- what's on those particles and
10:01:29 10 analyzing the content of those particles.

10:01:31 11 Q. Have you --

10:01:32 12 A. And from what I can tell, there was no
10:01:35 13 analysis of the chemistry or direct measurements of
10:01:39 14 the -- of what if any organ -- any infectious
10:01:45 15 organisms were on those particles.

10:01:47 16 Q. So would it help you if there were studies
10:01:49 17 that linked particle concentration to bacterial
10:01:52 18 concentration?

10:01:53 19 MR. GORDON: Object to the form of the
10:01:54 20 question.

10:02:00 21 A. Are you -- you mean --

10:02:02 22 Do you mean any studies or do you mean
10:02:03 23 studies particularly related to the Bair Hugger
10:02:06 24 device?

10:02:06 25 Q. I'm saying peer-reviewed literature that

10:02:10 1 would conclude that particles are linked to bacteria.

10:02:15 2 MR. GORDON: Object to the form of the
10:02:16 3 question.

10:02:17 4 A. The parti -- I -- I --

10:02:19 5 Yeah, I -- I don't under --

10:02:20 6 Q. Okay. I'll rephrase.

10:02:22 7 Would it help if there was peer-reviewed
10:02:26 8 literature which concluded that as the number of
10:02:29 9 particles increase, so too do the number of bacteria?

10:02:33 10 MR. GORDON: Object to the form of the
10:02:36 11 question.

10:02:36 12 A. Always?

10:02:36 13 Q. In a randomized controlled trial in
10:02:39 14 orthopedic surgeries.

10:02:41 15 A. So you're analyzing the -- the particles
10:02:44 16 that are in the -- on the operating room during --
10:02:47 17 during orthopedic surgery --

10:02:49 18 Q. Yes.

10:02:50 19 A. -- and -- and looking at -- at --

10:02:55 20 Yeah. If -- if there were -- if -- if I had
10:03:01 21 seen reports of that, I -- I would find that more
10:03:03 22 convincing, yes.

10:03:06 23 Q. And that would allow you to determine
10:03:08 24 whether an increase in particles could be linked to
10:03:12 25 bacteria.

10:03:14 1 A. It's a possibility. Again, it's -- it's --
10:03:19 2 from when --

10:03:20 3 When I say "indirect," the direct evidence
10:03:23 4 is ultimately the infection. That's the --

10:03:27 5 Q. Okay.

10:03:28 6 A. That's the event you want to look at and
10:03:31 7 that's -- that's the event that's of most interest.
10:03:34 8 But the event you're talking about is whether or not
10:03:36 9 there's something on the particles.

10:03:38 10 Q. So if deep joint infection is the outcome of
10:03:41 11 interest, --

10:03:41 12 A. Yes.

10:03:42 13 Q. -- it would be especially helpful if there
10:03:44 14 was an article that linked particles to bacteria, and
10:03:48 15 what I mean by that is that the more particles, the
10:03:51 16 more bacteria, but also found that the more bacteria,
10:03:54 17 the greater risk of infection.

10:03:56 18 A. Yes.

10:03:57 19 Q. That would be very helpful evidence in
10:04:01 20 determining whether the Bair Hugger increases the risk
10:04:03 21 of infection.

10:04:06 22 A. Well it's -- it's not directly related to
10:04:09 23 the Bair Hugger, but it would be -- yeah, it --
10:04:14 24 it's -- it's helping to pose -- to understand what the
10:04:21 25 potential mechanism might be.

10:04:23 1 Q. What about studies that have -- that would
10:04:25 2 have concluded that the Bair -- Bair Hugger actually
10:04:29 3 increases the number of bacteria at the surgical site,
10:04:32 4 would that be helpful?

10:04:35 5 A. Yes.

10:04:37 6 Q. And studies that show that the Bair Hugger
10:04:39 7 increases the number of particles at the surgical
10:04:43 8 site.

10:04:45 9 A. Yes. Compared to, you know, whatever the
10:04:48 10 comparison group is, yes.

10:04:54 11 Q. Did you review any articles involving the
10:04:58 12 subject matter we just discussed, which is the
10:05:01 13 relationship of particles to bacteria and bacteria to
10:05:03 14 deep joint infection?

10:05:05 15 A. That was not really part of my -- my review,
10:05:07 16 no.

10:05:08 17 Q. So you have not reviewed the article by
10:05:11 18 Gregory Stocks; correct?

10:05:13 19 A. No.

10:05:13 20 Q. You have not reviewed the article by
10:05:16 21 Darouiche et al; correct?

10:05:18 22 A. Correct.

10:05:18 23 Q. You have not reviewed the article by
10:05:21 24 Moretti.

10:05:22 25 A. Correct.

10:05:46 1 (Exhibit 7 was marked for
10:05:48 2 identification.)

10:05:48 3 BY MR. SACCHET:

10:05:51 4 Q. Doctor, this is an article authored by
10:05:53 5 Gregory Stocks; correct?

10:05:54 6 A. Yes.

10:05:56 7 Q. The title of the article is "Predicting
10:06:00 8 bacterial populations based on airborne particulates:
10:06:04 9 A study performed in nonlaminar flow operating rooms
10:06:06 10 during joint arthroplasty surgery;" correct?

10:06:10 11 A. That's the correct title, yes.

10:06:12 12 Q. The title involves the same subject matter
10:06:13 13 that we have just been discussing, which is the
10:06:16 14 relationship of particles to bacteria in orthopedic
10:06:18 15 surgeries; correct?

10:06:19 16 MR. GORDON: Object to the form of the
10:06:20 17 question, lack of foundation.

10:06:22 18 If you want him to read -- read it so he can
10:06:24 19 answer the question --

10:06:25 20 MR. SACCHET: I asked if the title reflects
10:06:28 21 the subject matter that we have discussed. I said
10:06:30 22 nothing about the article itself.

10:06:33 23 A. It appears to, yes.

10:06:37 24 Q. And if I could turn your attention to the
10:06:39 25 bottom right-hand corner of the first page, do you see

10:06:47 1 the paragraph beginning, "The purpose of this study
10:06:50 2 was to determine whether the density of airborne
10:06:53 3 particulates at the surgery site and various behaviors
10:06:56 4 of operating room personnel can be used to predict the
10:06:59 5 density of viable airborne bacteria (ie, colony-
10:07:04 6 forming units (CFU) at the surgery site during hip and
10:07:07 7 knee joint arthroplasty?"

10:07:09 8 A. Yes.

10:07:10 9 Q. This --

10:07:11 10 The purpose of this article was to determine
10:07:12 11 whether particulates are related to bacteria in
10:07:16 12 orthopedic surgery; correct?

10:07:17 13 A. Yes.

10:07:20 14 Q. If you could turn to the third page of the
10:07:23 15 study in the "RESULTS" section on the right-hand
10:07:41 16 column in the first full paragraph that begins "Table
10:07:46 17 2..." Do you see that?

10:07:49 18 A. Yes.

10:07:49 19 Q. The last sentence of that paragraph states,
10:07:54 20 "Neither sex nor surgery type was significantly
10:07:58 21 related to the square root CFU/m cubed;" correct?

10:08:08 22 I guess it's the second sentence. I
10:08:10 23 apologize.

10:08:10 24 A. Oh, oh, I -- okay. I was looking at the --

10:08:15 25 Q. Do you see the third sentence?

10:08:18 1 A. "...nor surgery type...", that's what it
10:08:23 2 says.

10:08:23 3 Q. Yeah. And the second --

10:08:24 4 And the next sentence says, "Surgery
10:08:27 5 duration, 5 micron to 9.99 micron particles per meter
10:08:33 6 cubed, greater than or equal to 10 micron particles
10:08:38 7 count per m cubed and staff count were each
10:08:42 8 significantly related (with a p-value of less than
10:08:46 9 .05) to the square root of the CFU per meters cubed;"
10:08:51 10 correct?

10:08:52 11 A. That's what it says, yes.

10:08:57 12 Q. Turning to the next page, in the right-hand
10:09:01 13 column, the first full paragraph begins with, "The
10:09:05 14 finding of a correlation..." Do you see that?

10:09:07 15 A. Yes.

10:09:08 16 Q. It states, "The finding of a correlation
10:09:11 17 between the number of 10 micron particles per meter --
10:09:14 18 per m cubed and CFU per m cubed at the surgical site
10:09:18 19 has several important implications. First, it
10:09:21 20 supports airborne parti -- particulate contamination
10:09:23 21 of the wound as a source of postoperative infection in
10:09:26 22 joint arthroplasty, as emphasized by Edmiston et al."
10:09:31 23 Do you see that?

10:09:32 24 A. Yes.

10:09:33 25 Q. And finally on the last page, the last

10:09:37 1 paragraph of text, do you see where it starts, "We
10:09:41 2 have found...?"

10:09:41 3 A. Yes.

10:09:42 4 Q. And it relates that, "We have found that the
10:09:45 5 number of airborne particulates greater than 10
10:09:47 6 microns was correlated with the number of CFUs grown
10:09:50 7 from the air sampled within the sterile field
10:09:53 8 approximately 40 centimeters from surgical incision."
10:09:57 9 Do you see that?

10:09:57 10 A. Yes.

10:09:58 11 Q. Do you have any reason to doubt the
10:09:59 12 conclusions of Stocks et al?

10:10:03 13 A. I have not --

10:10:04 14 This is the first I've -- first I've seen
10:10:06 15 this paper, so I would have to study it and -- to get
10:10:12 16 a better understanding of their methodology and what
10:10:14 17 they had done to -- to reach an opinion on this paper.

10:10:17 18 Q. Would it help you if one of 3M's past
10:10:23 19 experts had opined that the methods were good?

10:10:27 20 MR. GORDON: Object to the form of the
10:10:28 21 question.

10:10:28 22 A. No.

10:10:28 23 Q. Do you know Mr. Russ -- Mr. Russell
10:10:31 24 Olmstead, an epidemiologists and infectious --

10:10:36 25 A. No, I don't know him.

10:10:37 1 Q. -- disease doctor?

10:10:38 2 A. No, I don't know him.

10:10:39 3 Q. So you're not aware that he has stated that
10:10:41 4 the methods of Stocks are well done.

10:10:43 5 MR. GORDON: Object to the form of the
10:10:44 6 question.

10:10:47 7 A. I am not aware of what he -- what he has
10:10:50 8 said about this paper. I'm not familiar with it.

10:11:03 9 (Exhibit 8 was marked for
10:11:05 10 identification.)

10:11:05 11 BY MR. SACCHET:

10:11:07 12 Q. The subject line of this e-mail is "Stocks
10:11:10 13 Papers;" correct?

10:11:17 14 A. Yes.

10:11:21 15 Q. In the e-mail at the top we have a statement
10:11:25 16 from Mr. Gary Hansen to a Mr. Russell Olmstead
10:11:29 17 stating, "Could you send me a copy of the older Stocks
10:11:31 18 paper? AJIC does not sell them on line." Do you see
10:11:36 19 that?

10:11:36 20 A. Yes.

10:11:37 21 Q. And in the e-mail below that there are two
10:11:40 22 paragraphs; correct?

10:11:41 23 A. Yes.

10:11:42 24 Q. And the text is from Russell Olmstead, do
10:11:46 25 you see that?

10:11:48 1 A. Yes.

10:11:48 2 Q. And the first line says, "Hi Gary: fairly
10:11:51 3 remarkable paper given an ability to present during
10:11:54 4 actual procedures. I had not seen it so thanks for
10:11:57 5 bringing it to my attention. Demonstrates that pre
10:12:00 6 press page is useful place to visit often. It is
10:12:03 7 difficult to get IRB approval for such investigations.
10:12:06 8 I don't know the authors but the methods employed are
10:12:09 9 very good and I like the use of electronic particle
10:12:12 10 counts AND bacterial air sampling. Very helpful
10:12:15 11 picture of what happens in a typical non-
10:12:17 12 unidirectional HVAC design." Do you see that?

10:12:20 13 A. Yes.

10:12:22 14 Q. Do you have any reason to doubt that the
10:12:24 15 methods in this paper are anything but well designed?

10:12:27 16 MR. GORDON: Object to the form of the
10:12:28 17 question, also lack of foundation.

10:12:33 18 A. I don't un -- I mean I -- I -- that's --

10:12:39 19 That's this person's review of it, that's
10:12:46 20 his opinion of it. I agree -- I agree that that's his
10:12:51 21 opinion. I don't have an opinion on it because I have
10:12:53 22 not reviewed it.

10:12:54 23 Q. But you have seen that this article has
10:12:56 24 concluded that there is a link between airborne
10:12:59 25 particulates and bacteria; correct?

10:13:01 1 A. I've --

10:13:03 2 You just read me the paragraph, and I agree
10:13:05 3 that you've read them correctly to me.

10:13:08 4 Q. And as we established earlier, you said it
10:13:10 5 would be helpful if there was peer-reviewed literature
10:13:13 6 concluding that there was a link between particles and
10:13:15 7 bacteria; correct?

10:13:17 8 A. Well it would be helpful if I -- if it
10:13:19 9 was not only peer-reviewed but I had a chance to
10:13:22 10 review it.

10:13:22 11 Q. So --

10:13:23 12 A. I'm not going to take a peer-reviewed
13 article --

10:13:26 14 You know, every peer-reviewed article is
10:13:29 15 not -- is not -- not appro -- not correct, --

10:13:32 16 Q. Okay.

10:13:33 17 A. -- so I need --

10:13:34 18 One needs a chance to actually review the
10:13:36 19 science and digest what -- what was -- the work that
10:13:39 20 was actually done to reach a conclusion.

10:13:41 21 Q. So you did not review this article in
10:13:43 22 opining that particles are at most an indeterminate
10:13:46 23 outcome of deep joint infection.

10:13:49 24 A. That's correct.

10:13:49 25 Q. You also said that it would be helpful if

10:13:51 1 there were articles that concluded that particles were
10:13:54 2 not only related to bacteria but also that bacteria
10:13:57 3 was related to deep joint infection; correct? That's
10:14:01 4 what you testified to.

10:14:02 5 A. Yes.

10:14:03 6 Q. Have you reviewed any such articles,
10:14:07 7 professor?

10:14:11 8 A. No, I haven't. I mean it's -- it's -- this
10:14:14 9 is not --

10:14:15 10 That particular part of it is not really my
10:14:18 11 area.

10:14:18 12 Q. So it's not your area, but you concluded
10:14:21 13 that particles are at most an indeterminate outcome of
10:14:24 14 infection.

10:14:28 15 A. I --

10:14:30 16 The infection is the ultimate outcome that I
10:14:37 17 was interested in in looking at the McGovern paper, so
10:14:44 18 it's the occurrence of the infection which is -- which
10:14:48 19 is the outcome that I was most interested in. Whether
10:14:53 20 there's infectious organisms on particles is basically
10:15:01 21 an intermediate step which would be helpful of
10:15:05 22 understanding, perhaps, how they got there.

10:15:08 23 Q. Okay.

10:15:09 24 A. But it's not the outcome that I was
10:15:12 25 particularly interested in.

10:15:14 1 Q. So let's look at this paper which --

10:15:16 2 THE REPORTER: Just a moment.

10:15:27 3 (Exhibit 9 was marked for

10:15:28 4 identification.)

10:15:28 5 BY MR. SACCHET:

10:15:32 6 Q. The title of this article is the

10:15:34 7 "Association of Airborne Microorganisms in the

10:15:36 8 Operating Room With Implant Infections: A Randomized

10:15:39 9 Controlled Trial;" correct?

10:15:40 10 A. Yes.

10:15:41 11 Q. The title of this article relates to the

10:15:45 12 relationship of airborne microorganisms to infection;

10:15:50 13 correct?

10:15:50 14 A. That's what the title is, yes.

10:15:52 15 Q. That is the subject matter by which you

10:15:54 16 testified one minute ago that it would be helpful to

10:15:57 17 review to determine whether bacteria are related to

10:16:00 18 the outcome of interest, deep joint infection;

10:16:03 19 correct?

10:16:03 20 A. That would be helpful for under -- to

10:16:06 21 perhaps get an understanding of the mechanisms, yes.

10:16:09 22 Q. The objective of the paper was to, quote,

10:16:12 23 "To evaluate the association of airborne colony-

10:16:16 24 forming units (CFU) at incision sites during

10:16:18 25 implantation of prostheses with the incidence of

10:16:22 1 either incisional or prosthesis-related surgical site
10:16:25 2 infections;" correct?

10:16:26 3 A. Yes.

10:16:27 4 Q. This was a randomized controlled trial;
10:16:31 5 correct?

10:16:31 6 A. That's what it says.

10:16:32 7 Q. Randomized controlled trials are first-tier
10:16:36 8 scientific evidence; correct?

10:16:38 9 A. They can be, yes.

10:16:40 10 Q. Are there other types of studies that are
10:16:42 11 given more weight than RCTs?

10:16:45 12 A. In general, they're -- they're given the
10:16:47 13 most weight, yes, if they're well done.

10:16:55 14 Q. If we could turn to page six, and you'll see
10:17:00 15 the pages are listed on the top of the paper, under
10:17:10 16 the header "CFU and Particulate Densities and
10:17:13 17 Infection," do you see that heading?

10:17:16 18 A. Yes.

10:17:18 19 Q. It states, "CFU density at incision sites
10:17:21 20 was significantly related to incidence of implant
10:17:24 21 infections (with a p-value of .021), but not of
10:17:28 22 incisional infections (with a p-value of .687). Every
10:17:34 23 10 CFU per m cubed increase in median CFU denies
10:17:39 24 approximately doubled the probability of implant
10:17:41 25 infection (Figure 4). CFU density was positively

10:17:45 1 related to total particulate density (with a p-value
10:17:49 2 of less than .001) in the control group, indicating
10:17:54 3 that airborne particle counts may be used as a proxy
10:17:57 4 for ambient CFU density." Do you see that?

10:18:00 5 A. Yes.

10:18:06 6 Q. On page eight of this study, very last
10:18:14 7 paragraph, do you see that?

10:18:20 8 A. Yes.

10:18:22 9 Q. "In conclusion, our results indicate that
10:18:24 10 CFU contamination of air at the incision site is a
10:18:27 11 risk factor for implant but not incisional infections.
10:18:32 12 CFU contamination is related to the particulate
10:18:35 13 density in the air at the incision site, and both CFU
10:18:39 14 and particulate density are a function of the number
10:18:42 15 of people in the operating room. Limiting airborne
10:18:45 16 CFU contamination at the incision site can be expected
10:18:48 17 to lower implant infection risk."

10:18:51 18 Did I read that correctly?

10:18:52 19 A. Yes.

10:18:54 20 Q. You have no reason to doubt that conclusion;
10:18:56 21 do you?

10:18:56 22 MR. GORDON: Object to the form of the
10:18:58 23 question, lack of foundation.

10:19:00 24 A. That conclusion would be based on the -- the
10:19:06 25 whole study, and you've just given me this study, and

10:19:10 1 I haven't had a chance to really study this paper, so
10:19:12 2 I would -- I would need to study the paper in order
10:19:15 3 to -- to have an opinion on that conclusion.

10:19:19 4 Q. You didn't study the paper, but you did
10:19:21 5 conclude that particles are at best an indeterminate
10:19:24 6 outcome of infection; correct?

10:19:26 7 MR. GORDON: Object to the form of the
10:19:27 8 question.

10:19:31 9 A. I -- I concluded, as I've -- I've explained
10:19:37 10 the reason my --

10:19:39 11 What I meant when I said that is that that
10:19:43 12 was a diff -- an intermediate outcome. I mean what
10:19:48 13 you have read to me does not --

10:19:53 14 I didn't see that the Bair Hugger was
10:19:55 15 involved with this. Is that correct?

10:19:58 16 Q. The Bair Hugger was not involved in this
10:20:00 17 study.

10:20:00 18 A. Okay.

10:20:01 19 Q. Would it help you if I showed you studies --

10:20:03 20 A. If you --

10:20:03 21 If this study had used the Bair Hugger, that
10:20:05 22 would help.

10:20:06 23 Q. Would it help you if I showed you studies
10:20:08 24 showing the Bair Hugger increasing particles or
10:20:10 25 increasing bacteria?

10:20:11 1 MR. GORDON: Object to the form of the
10:20:13 2 question, compound.

10:20:18 3 A. Well which -- which --

10:20:19 4 What is the outcome that you're -- you're
10:20:21 5 showing me?

10:20:22 6 Q. So we have a study here, and you would agree
10:20:25 7 that it has concluded that particles have a
10:20:29 8 relationship to bacteria and bacteria has a
10:20:32 9 relationship to deep joint infection; correct?

10:20:35 10 MR. GORDON: Are you talking about Exhibit
10:20:36 11 8?

10:20:36 12 MR. SACCHET: I'm talking about Exhibit --

10:20:38 13 A. Exhibit 9?

10:20:39 14 MR. SACCHET: -- 9.

10:20:40 15 A. What?

10:20:41 16 Q. This paper concludes --

10:20:42 17 A. This one is 9.

10:20:44 18 Q. Darouiche, Exhibit 9.

10:20:46 19 A. Yeah, okay.

10:20:47 20 Q. -- that the amount of particles is related
10:20:49 21 to the amount of bacteria; correct?

10:20:51 22 A. That's what they -- that's this paper --
23 that's --

10:20:55 24 That's what they found in -- in this trial.

10:20:57 25 Q. Yes.

10:20:58 1 A. That appears to be from the limited reading
10:20:59 2 that -- that we've just done.

10:21:01 3 Q. You have seen that it's a randomized
10:21:03 4 controlled trial.

10:21:04 5 A. I've seen it described there. I have not
10:21:06 6 reviewed exactly what they did, how they did the
10:21:09 7 randomization.

10:21:10 8 Q. And this paper also concludes that the
10:21:13 9 number of bacteria increase -- as the bacteria
10:21:18 10 increases, that increases the risk of DJI, deep joint
10:21:22 11 infection; correct?

10:21:23 12 A. That is their -- that is their conclusion,
10:21:25 13 yes.

10:21:26 14 Q. If this paper did not involve the Bair
10:21:28 15 Hugger, would it help you to see studies that conclude
10:21:30 16 that the Bair Hugger increases particles?

10:21:34 17 A. It would -- it would help to see that it
10:21:37 18 increases particles and it increases the -- the risk
10:21:41 19 of infection.

10:21:43 20 Q. If this paper establishes a link between
10:21:46 21 particles, bacteria and infection, --

10:21:48 22 A. Yes.

10:21:49 23 Q. -- and the Bair Hugger increases particles,
10:21:52 24 is it your testimony that one cannot also conclude
10:21:56 25 that the Bair Hugger increases bacteria?

10:21:58 1 MR. GORDON: Object to the form of the
10:21:59 2 question, lack of foundation, incomplete hypothetical.

10:22:03 3 Q. It's a simple syllogism: Premise one,
10:22:07 4 particles relate to bacteria; premise two, bacteria
10:22:11 5 relates to deep joint infection. Q.E.D., if Bair
10:22:14 6 Hugger increases particles, does it increase bacteria?

10:22:17 7 MR. GORDON: Object to the form of the
10:22:19 8 question, lack of foundation, it's an incomplete
10:22:22 9 hypothetical.

10:22:23 10 A. You haven't -- you -- you haven't shown the
10:22:25 11 whole -- whole scenario.

10:22:28 12 Q. What's the whole scenario?

10:22:30 13 A. Well that -- that you used the Bair -- used
10:22:34 14 the Bair Hugger --

10:22:34 15 Q. Yeah.

10:22:34 16 A. -- and that in turn increases your risk
10:22:37 17 of -- the risk of infection.

10:22:38 18 Q. So you would only conclude that the Bair
10:22:42 19 Hugger increases infection if there was a study
10:22:45 20 showing the Bair Hugger increases the risk of
10:22:48 21 infection.

10:22:49 22 MR. GORDON: Object to the form of the
10:22:51 23 question.

10:22:53 24 A. I would -- I would want to see a well-
10:22:58 25 controlled study that showed that use of the Bair

10:23:01 1 Hugger during surgery increased risk of -- of -- of
10:23:05 2 infection.

10:23:06 3 Q. Epidemiology considers more than evidence
10:23:10 4 that draws a unidirectional link between a variable
10:23:16 5 and an outcome; correct?

10:23:17 6 MR. GORDON: Object to the form of the
10:23:19 7 question.

10:23:19 8 A. Yeah. I don't understand the question.

10:23:21 9 Q. Part of epidemiology considers the mechanism
10:23:24 10 of infection; correct?

10:23:25 11 A. That's one aspect of interest, yes.

10:23:27 12 Q. That relates to the coherency of whether a
10:23:33 13 cause increases an outcome; correct?

10:23:35 14 A. That's one of the considerations, is the
10:23:38 15 mech -- is -- is the mechanism.

10:23:39 16 Q. And when you consider a mechanism, you can
10:23:42 17 consider intermediate outcomes that lend biological
10:23:47 18 plausibility to causal inference; correct?

10:23:50 19 A. Well intermediate outcomes very often
10:23:53 20 have -- have -- have not worked out in ep -- in
10:23:58 21 epidemiological studies. Sometimes -- sometimes --

10:24:00 22 Q. I'm going to -- I'm going to interrupt you
10:24:02 23 and mover to strike. The question is --

10:24:04 24 MR. GORDON: No. Let him answer the
10:24:04 25 question, then you can move to strike if you don't

10:24:06 1 like it, but don't cut -- don't cut him off during
10:24:11 2 the -- his answer.

10:24:11 3 A. I mean there -- there are many -- there are
10:24:14 4 many studies that look at intermediate outcomes
10:24:18 5 that --

10:24:18 6 Q. Okay.

10:24:19 7 A. -- that you find an association with
10:24:23 8 intermediate outcomes, but then the main one of
10:24:25 9 interest, which is the primary -- primary point, is --
10:24:28 10 is not in fact demonstrated. And it -- and it could
10:24:31 11 be due to a number of things; it may be that you have
10:24:34 12 the wrong idea of what the actual mechanism is.

10:24:38 13 Q. In your view, what is the dose at issue in
10:24:42 14 this litigation?

10:24:43 15 MR. GORDON: Object to the form of the
10:24:44 16 question, lack of foundation.

10:24:46 17 A. Dose.

10:24:46 18 Q. Dose is one of the criteria for determining
10:24:49 19 causal inference; correct?

10:24:55 20 A. One of the things that's often of interest
10:24:59 21 is -- is not a -- a particular dose.

10:25:03 22 What dose do you have in mind? I didn't --

10:25:05 23 Q. As something increases, an outcome could
10:25:07 24 increase.

10:25:07 25 A. Okay. That -- so that would be a

10:25:09 1 dose/response relationship. A dose/response
10:25:12 2 relationship would be -- would be one important thing
10:25:15 3 to look at.

10:25:16 4 Q. What --

10:25:16 5 In your view what is -- what is the material
10:25:18 6 dose with respect to whether the Bair Hugger increases
10:25:20 7 infection?

10:25:21 8 MR. GORDON: Object to the form of the
10:25:22 9 question, lack of foundation.

10:25:25 10 A. I don't -- I don't recall seeing in any of
10:25:30 11 the -- the -- the -- for example, the McGovern study,
10:25:35 12 anything on dose of Bair Hugger. You either use it or
10:25:39 13 you don't. It's a binary --

10:25:41 14 Q. What causes infection?

10:25:43 15 MR. GORDON: Object -- same objections.

10:25:45 16 A. What causes --

10:25:46 17 Q. What -- what -- what thing leads to an
10:25:51 18 infection? Particles? Bacteria? What?

10:25:56 19 MR. GORDON: Object.

10:25:56 20 A. Bacteria.

10:25:57 21 Q. So is bacteria the dose, because the more
10:25:59 22 bacteria you have, the greater incidence of deep joint
10:26:03 23 infection?

10:26:04 24 MR. GORDON: Object to the form of the
10:26:05 25 question, lack of foundation.

10:26:06 1 MR. SACCHET: We've just reviewed a study on
10:26:08 2 the topic, so there is foundation.
10:26:10 3 A. But --
10:26:11 4 MR. GORDON: I mean --
10:26:12 5 A. -- there's no evidence of what the dose --
10:26:14 6 the dose of bacteria is that's coming from that --
10:26:17 7 from the Bair Hugger.
10:26:17 8 Q. If the Bair Hugger increases the amount of
10:26:20 9 bacteria --
10:26:21 10 A. But you're not measuring the dose.
10:26:24 11 Q. If it is found that the Bair Hugger
10:26:25 12 increases the amount of bacteria --
10:26:28 13 A. Well the dose/response relationship is that
10:26:31 14 you measure different doses and that affects your
10:26:36 15 risk.
10:26:36 16 Q. Would it help you if there were --
10:26:37 17 A. No one has measured the dose -- the dose of
10:26:41 18 bacteria that's come -- that's come from the Bair
10:26:42 19 Hugger.
10:26:42 20 Q. Do you know that a single bacterium can
10:26:45 21 cause a deep joint infection?
10:26:46 22 A. Yes.
10:26:47 23 Q. So does dose matter if the more bacteria you
10:26:52 24 have and that one bacteria can cause an infection?
10:26:55 25 MR. GORDON: Object to form. Object to the

10:26:57 1 form of the question, lack of foundation.

10:27:03 2 Q. If -- if one bacteria can cause an infection
10:27:07 3 and the more bacteria that you have increases the risk
10:27:10 4 of infection, it stands to reason that the
10:27:14 5 dose/response relationship as to how much the Bair
10:27:17 6 Hugger might produce in -- in terms of bacteria is not
10:27:22 7 the relevant question.

10:27:23 8 MR. GORDON: Object to form, also -- also
10:27:25 9 lack of foundation.

10:27:27 10 A. I mean you're -- you're not --
10:27:29 11 There's no data that you're showing me
10:27:32 12 that -- that relates -- that I have seen --

10:27:35 13 Q. Yeah.

10:27:36 14 A. -- related to the Bair Hugger --

10:27:39 15 Q. Okay.

10:27:39 16 A. -- that indicates the dose of bacteria that
10:27:43 17 each of these patients was exposed to.

10:27:47 18 Q. Would a study showing that the Bair Hugger
10:27:49 19 increases the amount of bacteria at the surgical site
10:27:52 20 help you?

10:27:54 21 A. You -- you --

10:27:57 22 To establish a dose/response relationship,
10:28:01 23 you need to know what the dose is.

10:28:03 24 Q. So the only way that you would draw any
10:28:06 25 inference about whether the number of bacteria from

10:28:10 1 the Bair Hugger increases the risk of infection is if
10:28:13 2 you knew the dose/response relationship?

10:28:16 3 MR. GORDON: Object to the form of the
10:28:17 4 question.

10:28:17 5 A. You're the one that raised the issue of
10:28:20 6 there being a dose/response relationship.

10:28:24 7 Q. And my question is: What is the dose at
10:28:27 8 issue? Bacteria?

10:28:29 9 A. I guess --

10:28:29 10 Well I don't know. You're the one that
10:28:32 11 raised it. I haven't -- I've -- as I've -- as I've
10:28:36 12 said, I have not seen anything in these studies that
10:28:40 13 measures dose. It could be the num -- the level of
10:28:43 14 bacteria, it could be how long you were in surgery, it
10:28:46 15 could be, you know, how -- I don't know if there's
10:28:51 16 different settings of these -- of these -- on -- on
10:28:55 17 the Bair Hugger, but I mean there are -- or -- or for
10:28:59 18 that matter any heating -- warming device, so it's --
10:29:07 19 Those would be some measurements of -- of
10:29:07 20 dose.

10:29:08 21 Q. Okay.

10:29:08 22 A. And these studies did not do that.

10:29:10 23 Q. Okay.

10:29:13 24 MR. SACCHET: We're going to pass you what
10:29:14 25 will be marked as Exhibit 10.

10:29:22 1 (Exhibit 10 was marked for
10:29:23 2 identification.)
10:29:23 3 BY MR. SACCHET:
10:29:25 4 Q. Have you seen this document before,
10:29:27 5 Professor Holford?
10:29:29 6 A. No, I have not.
10:29:31 7 Q. The title of the document is the
10:29:35 8 "Proceedings of the International Consensus Meeting on
10:29:39 9 Periprosthetic Joint Infection;" correct?
10:29:42 10 A. Yes.
10:29:42 11 Q. Do you know who Javad Parvizi is?
10:29:45 12 A. No, I do not.
10:29:47 13 Q. So you don't know that he is a consultant
10:29:47 14 for 3M?
10:29:48 15 A. No, I don't.
10:29:49 16 Q. Okay. If you turn to page six, do you see
10:29:52 17 the 3M logo?
10:30:03 18 A. Yes.
10:30:04 19 Q. And above that we see the text "Platinum
10:30:11 20 Sponsor;" correct?
10:30:11 21 A. Yes.
10:30:12 22 Q. So 3M was a platinum sponsor of this
10:30:16 23 consensus; correct?
10:30:16 24 A. Apparently.
10:30:16 25 Q. The next page is page 114.

10:30:18 1 MR. GORDON: Counsel, is there --

10:30:19 2 Where is page seven through 113?

10:30:22 3 MR. SACCHET: They are not included.

10:30:23 4 MR. GORDON: Well I'm going to object to

10:30:26 5 this document on the grounds of completeness.

10:30:28 6 MR. SACCHET: That's fine.

10:30:29 7 Q. Page 114 is entitled "Workgroup 4;" correct?

10:30:33 8 A. Yes.

10:30:33 9 Q. On the operating room -- "Operative

10:30:37 10 Environment;" correct?

10:30:37 11 A. Yes.

10:30:37 12 Q. And beneath that we see numerous

10:30:41 13 delegates -- delegates, all of whom have M.D.s;

10:30:45 14 correct?

10:30:45 15 A. They seem to, yes.

10:30:46 16 Q. Okay. On page 115, question one states, "Do

10:30:52 17 numbers of bacteria arriving in the surgical wound

10:30:54 18 correlate directly with probability of SSI?" Do you

10:30:58 19 see that?

10:30:59 20 A. Yes.

10:30:59 21 Q. And the consensus statement reads, "We

10:31:01 22 recognize that the probability of surgical site

10:31:04 23 infection correlates directly with the quantity of

10:31:06 24 bacteria that reach the wound. Accordingly we support

10:31:11 25 strategies to lower particulate and bacterial counts

10:31:15 1 at surgical wounds.

10:31:17 2 "Delegate Vote: Agree: 97 percent, (Strong
10:31:21 3 consensus)."

10:31:22 4 Do you see that, professor?

10:31:23 5 A. Yes, I do.

10:31:24 6 Q. Do you have any reason to doubt the
10:31:26 7 consensus statement of these medical doctors?

10:31:29 8 MR. GORDON: Object to the form of the
10:31:31 9 question.

10:31:35 10 A. I -- I mean that's their opinion. That's --
10:31:38 11 Yes.

10:31:39 12 Q. And this opinion states that the number of
10:31:43 13 bacteria at the surgical site relates to the incidence
10:31:46 14 of surgical-site infection; correct?

10:31:48 15 A. Yes.

10:31:49 16 Q. Okay. Does that explain that the number of
10:31:54 17 bacteria could be viewed as the dose at issue with
10:31:58 18 respect to surgical-site infection?

10:32:00 19 MR. GORDON: Object to the form of the
10:32:01 20 question, also lack of foundation.

10:32:05 21 A. The -- the -- the problem I -- I --

10:32:09 22 I mean I'm not sure what connection you're
10:32:11 23 looking at. As the statement is --

10:32:14 24 Q. Okay.

10:32:14 25 A. -- as -- if the --

10:32:16 1 If you have different levels of -- of
10:32:22 2 bacteria at the surgical site, you will affect the
10:32:25 3 risk.

10:32:26 4 Q. Uh-huh. And the more bacteria at the
10:32:28 5 surgical site, the increased risk of infection.

10:32:32 6 A. That's -- that's what they're -- they're
10:32:34 7 concluding, yes.

10:32:36 8 Q. Okay. And question two says, "Do numbers of
10:32:39 9 bacteria in the operating room environment correlate
10:32:41 10 directly with the probability of surgical site
10:32:44 11 infection?" And the consensus on that states, "We
10:32:48 12 recognize that airborne particulate bacteria are a
10:32:51 13 major source of contamination in the operating room
10:32:53 14 environment and that bacteria shed by personnel are
10:32:56 15 the predominant source of these particles. The focus
10:32:59 16 of our recommendation is to reduce the volume of
10:33:01 17 bacteria in the operating room with particular
10:33:04 18 attention to airborne particles."

10:33:07 19 A. Okay.

10:33:08 20 Q. This consensus draws a relationship between
10:33:15 21 bacteria and particles; correct?

10:33:18 22 A. Yes.

10:33:19 23 Q. And 93 percent of the delegates agreed to
10:33:23 24 that link.

10:33:26 25 A. Well they're --

10:33:28 1 It's not just particles, they're talking
10:33:31 2 about bacteria. Right?

10:33:33 3 Q. The relationship of part --

10:33:35 4 A. Do the -- do the number of bacteria in the
10:33:36 5 operating room correlate directly with the probability
10:33:39 6 of surgical-site infection, so it's -- you --

10:33:42 7 I think you stated the question as
10:33:44 8 "particles."

10:33:45 9 Q. And it says there should be particular
10:33:47 10 attention to airborne particles; correct?

10:33:53 11 A. Where are you reading?

10:33:54 12 Q. From the consensus statement at the top of
10:33:57 13 page 116.

10:34:02 14 A. It's referring again to the bacterial
10:34:05 15 particles.

10:34:05 16 Q. And it says, "The focus of our
10:34:07 17 recommendation is to reduce the volume of bacteria in
10:34:11 18 the operating room with particular attention to
10:34:13 19 airborne particles;" correct?

10:34:15 20 A. Well, but the particles that they're
10:34:18 21 referring to are airborne particulate bacteria.

10:34:21 22 Q. Okay. Let's look at the justification,
10:34:23 23 which is the paragraph below that. The third
10:34:26 24 statement begins with "Bacteria can be considered..."
10:34:29 25 Do you see that?

10:34:31 1 A. The third --

10:34:33 2 Q. The third sentence. Do you see that?

10:34:37 3 A. Yes.

10:34:38 4 Q. "Bacteria can be considered as part of the
10:34:40 5 total mass of particulates in the air. Some studies
10:34:43 6 have suggested that the airborne parti -- particulate
10:34:46 7 count should be considered as a potential surrogate
10:34:49 8 for airborne microbial density. Others have found
10:34:54 9 correlation between the number of particles larger
10:34:56 10 than 10 micrometers with a density of viable bacteria
10:34:59 11 at the surgery measured by colony-forming units." Do
10:35:03 12 you see that?

10:35:03 13 A. Yes.

10:35:03 14 Q. So the justification for the consensus
10:35:06 15 statement involves the relationship between particles
10:35:09 16 and bacteria.

10:35:10 17 MR. GORDON: Object to the form of the
10:35:12 18 question, lack of foundation.

10:35:15 19 A. I mean there again, the --

10:35:19 20 I don't think the intent of the statement is
10:35:21 21 any old particle. They're interested in particles
10:35:27 22 that have bacteria on them.

10:35:30 23 Q. I'll read the sentence again.

10:35:32 24 A. Well that's what this sentence is, but I
10:35:33 25 mean this is what the question is.

10:35:35 1 Q. The justification for the answer draws a
10:35:39 2 link between airborne particles and bacteria; correct?

10:35:44 3 A. There --

10:35:45 4 Yes, they are saying there is a
10:35:48 5 relationship.

10:35:48 6 Q. And you have --

10:35:49 7 A. There often is a relationship.

10:35:51 8 Q. Okay.

10:35:51 9 A. That's what they're saying.

10:35:52 10 Q. You have no reason to doubt that
10:35:54 11 relationship; correct?

10:35:55 12 A. But the --

10:35:56 13 It depends on what the -- what the
10:36:00 14 conditions are in that particular operating room.

10:36:03 15 Q. You have no expertise in airborne particles
10:36:06 16 is your testimony from earlier this morning.

10:36:11 17 A. Okay. So I mean --

10:36:14 18 So I don't understand your question.

10:36:15 19 Q. So --

10:36:16 20 A. If you're saying I don't --

10:36:18 21 Q. You have a reason to doubt the conclusion
10:36:20 22 even though you don't have expertise in the subject
10:36:22 23 matter is my point.

10:36:24 24 A. I'm not --

10:36:25 25 MR. GORDON: Object to the form of the

10:36:26 1 question.

10:36:26 2 A. I'm not -- I'm -- I'm not dis -- disputing
10:36:30 3 what I think they are saying, --

10:36:32 4 Q. Okay.

10:36:33 5 A. -- which is that -- relates, again, to the
10:36:39 6 particles and what is -- what those particles are.

10:36:42 7 Q. So when they say there is a correlation
10:36:45 8 between the number of particulates with a density of
10:36:48 9 viable bacteria, you're interpreting that statement to
10:36:52 10 mean that those particles already are bacteria?

10:36:58 11 A. If you're in an environment that is somehow
10:37:05 12 spraying out part -- particles that are sterile, are
10:37:12 13 you -- are you going to use this -- are you using
10:37:14 14 this -- their statement here that you're increase --
10:37:19 15 you are at increased risk of infection? Is that what
10:37:23 16 you're arguing?

10:37:23 17 Q. If there is a correlation between the number
10:37:25 18 of particles and bacteria is what it says.

10:37:26 19 A. From the circumstances that I've described,
10:37:28 20 there's not going to be a correlation.

10:37:30 21 Q. That may be very well in some circumstances,
10:37:32 22 but --

10:37:32 23 A. Exactly.

10:37:35 24 Q. -- it varies in other circumstances
10:37:36 25 according to the consensus statement.

10:37:37 1 A. There are --

10:37:37 2 Exactly.

10:37:38 3 Q. So you would agree in some circumstances --

10:37:39 4 A. In some circumstances, yes.

10:37:40 5 Q. -- there is a relationship between particle
10:37:43 6 load and bacterial load.

10:37:44 7 A. In some circumstances.

10:37:45 8 Q. And in some circumstances the relationship
10:37:47 9 between bacterial load also relates to the increased
10:37:51 10 risk of infection; correct?

10:37:52 11 A. Yes.

10:37:55 12 Q. Are you aware that the Bair Hugger increases
10:37:59 13 particles in the operating room?

10:38:00 14 MR. GORDON: Object to the form of the
10:38:02 15 question.

10:38:06 16 A. I'm -- I'm aware that -- that some of
10:38:10 17 the -- some of the studies seem to suggest that
10:38:13 18 there -- that there is a -- an increase.

10:38:16 19 Q. I notice that you used the word "some" in
10:38:19 20 your report as well. That's true; correct?

10:38:22 21 A. I don't recall what I -- exactly what I --
10:38:24 22 my wording was.

10:38:25 23 Q. But your testimony today is that some
10:38:28 24 studies show an increase in particulate load over the
10:38:31 25 surgical site.

10:38:32 1 A. There have been some studies, yes.

10:38:35 2 Q. And some can include all as a logical
10:38:38 3 matter; correct?

10:38:38 4 A. Some can --

10:38:39 5 Q. Some can be all.

10:38:41 6 A. All studies have found this?

10:38:43 7 Q. I'm just saying it's -- there's --

10:38:45 8 There's no point in arguing over the
10:38:47 9 semantics, but have you read 3M's -- the deposition of
10:38:52 10 3M's corporate representative in this litigation?

10:38:54 11 A. No, I have not.

10:38:55 12 Q. You have not. So you're not aware that the
10:38:58 13 corporate representative for 3M testified that every
10:39:02 14 single study indicates that the Bair Hugger increases
10:39:05 15 the particle count over the surgical field?

10:39:07 16 MR. GORDON: Object to the form of the
10:39:09 17 question, assumes facts not in evidence, lack of
10:39:11 18 foundation.

10:39:12 19 A. I -- I have not seen that. I hadn't -- had
10:39:16 20 not seen that -- that testimony, so I --

10:39:19 21 I had not seen that statement.

10:39:32 22 MR. GORDON: Are we reaching a point where
10:39:34 23 we can take a quick break?

10:39:36 24 MR. SACCHET: In a little bit, yeah. I'll
10:39:38 25 try to move through this.

10:39:40 1 (Exhibit 11 was marked for

10:39:44 2 identification.)

10:39:44 3 BY MR. SACCHET:

10:39:50 4 Q. This on the cover page has been denoted as
10:39:53 5 the deposition of Albert Van Duren. Do you see that,
10:39:56 6 Dr. Holford?

10:39:57 7 A. Yes.

10:39:57 8 Q. Okay. And turning to the back side of the
10:40:03 9 paper, there are lines of testimony; correct? Do you
10:40:11 10 see page 258 internal?

10:40:15 11 A. Yes.

10:40:16 12 Q. Do you see lines five through 10?

10:40:19 13 A. Yes.

10:40:20 14 Q. Line five states: "Based on the data that
10:40:23 15 we have today, including the study funded by 3M as
10:40:27 16 well as other studies, every single study indicates
10:40:29 17 that the Bair Hugger increases the particle count over
10:40:32 18 the sterile field; correct?"

10:40:33 19 "Answer: In absolute numbers, yes.

10:40:36 20 "Question: Okay. And you have no internal
10:40:38 21 study to refute that; correct?

10:40:41 22 "No, we don't."

10:40:44 23 A. Okay.

10:40:45 24 Q. Does this clarify your position as to
10:40:49 25 whether some studies have shown an increase in

10:40:52 1 particles over the surgical site as a result of the
10:40:56 2 Bair Hugger?

10:40:56 3 MR. GORDON: Object to the form of the
10:40:57 4 question, lack of foundation.

10:40:59 5 A. There are some -- there are some studies.

10:41:03 6 Q. Does this --

10:41:04 7 A. I don't think --

10:41:05 8 Q. -- testimony from 3M use the word "all" or
10:41:07 9 "some?"

10:41:07 10 MR. GORDON: Object to the form of the
10:41:09 11 question, lacks foundation.

10:41:12 12 A. I mean I've -- I've -- what -- what you're
10:41:15 13 showing me is just this one -- one statement. I don't
10:41:17 14 know what all went before this. My impression from
10:41:21 15 what you just read is that when they say "all,"
10:41:24 16 there's a whole set of studies that came before this
10:41:29 17 and the "all" of refers to those.

10:41:31 18 Q. Do you know any studies that have not found
10:41:33 19 an increase in particles over the surgical site after
10:41:37 20 use of the Bair Hugger?

10:41:38 21 A. No, I don't.

10:41:41 22 Q. You reviewed the McGovern study; correct?

10:41:47 23 A. Yes. I don't recall that the -- I don't
10:41:50 24 recall the -- the McGovern study actually measuring
10:41:54 25 particles over the surgical -- over the surgical site.

10:41:57 1 Q. Is a bubble a particle?

10:42:01 2 A. The bubble part of it was not taking place
10:42:03 3 during -- during surgery.

10:42:04 4 Q. It was a simulated surgery; correct?

10:42:06 5 A. It was simulated.

10:42:07 6 Q. Right.

10:42:07 7 A. It was not the actual surgery.

10:42:09 8 Q. Fair enough. But they did find an increase
10:42:12 9 of bubbles over the surgical site from the use of the
10:42:14 10 Bair Hugger compared to a conductive warming device.

10:42:18 11 A. Yes. I read that part of it, yes.

10:42:20 12 Q. You reviewed the Legg studies; correct?

10:42:21 13 A. No, I don't think I did.

10:42:23 14 Q. You didn't. So you're not aware that the
10:42:26 15 2013 Legg study found a one-thousand-times increase in
10:42:31 16 particles over the surgical site from the use of the
10:42:33 17 Bair Hugger compared to a radiant warming device.

10:42:35 18 A. I'm not familiar with that study, no.

10:42:37 19 Q. You're not aware that the 2012 Legg study
10:42:41 20 also found a statistically significant increase in
10:42:43 21 particles over the surgical site after use of the Bair
10:42:46 22 Hugger device.

10:42:47 23 A. I am not familiar with that one.

10:42:49 24 Q. Have you reviewed the Belani study?

10:42:51 25 A. No.

10:42:51 1 Q. You're not aware that the Belani study found
10:42:54 2 that there was an increase in bubbles over the
10:42:58 3 surgical site after the use of the Bair Hugger
10:43:00 4 compared to a conductive warming device.

10:43:06 5 A. I'm not familiar with that, no.

10:43:07 6 Q. Have you reviewed the Sessler study?

10:43:09 7 A. No, I have not.

10:43:10 8 Q. You're not aware that the Sessler study also
10:43:13 9 found an increase in particles over the surgical site
10:43:15 10 from the use of the Bair Hugger when it was on versus
10:43:17 11 when it was off.

10:43:19 12 MR. GORDON: Object to the form of the
10:43:20 13 question, assumes facts not in evidence, misstates the
10:43:23 14 testimony.

10:43:24 15 A. I'm not familiar with the -- with the --
10:43:26 16 with the findings of that study, no.

10:43:34 17 Q. Have you reviewed any studies that show that
10:43:35 18 the Bair Hugger increases the amount of bacteria over
10:43:38 19 the surgical site?

10:43:46 20 A. No, I'm not familiar with that.

10:44:01 21 MR. SACCHET: Just maybe five more minutes.

10:44:11 22 (Exhibit 12 was marked for
10:44:13 23 identification.)

10:44:13 24 BY MR. SACCHET:

10:44:19 25 Q. The title of this article, professor, is

10:44:21 1 "Convection warmers -- a possible source of
10:44:23 2 contamination in laminar airflow operating theatres?"
10:44:27 3 Correct?
10:44:27 4 A. Yes.
10:44:29 5 Q. Do you see in the summary in the second line
10:44:42 6 from the bottom, it starts, "This study" -- or I
10:44:47 7 apologize. "A further small rise..." Do you see the
10:44:50 8 beginning of that sentence, third-to-the-last
10:44:52 9 statement in the abstract?
10:44:53 10 A. Yes.
10:44:54 11 Q. "A small -- A further small rise is seen
10:44:56 12 after the convection heaters were turned on when
10:44:58 13 applied to patients. This study showed that use of
10:45:01 14 warm air convection heaters on patients produced a
10:45:04 15 small increase in the number of colony forming units
10:45:06 16 in ultra-clean air theatres but the levels were
10:45:12 17 unlikely to have clinical significance." Do you see
10:45:12 18 that?
10:45:13 19 A. Yes.
10:45:13 20 Q. So this study, based on the summary -- and I
10:45:16 21 understand you have not reviewed it in whole -- does
10:45:17 22 conclude that there was as small increase in bacteria
10:45:19 23 from a convection warmer.
10:45:21 24 MR. GORDON: Object to the form of the
10:45:22 25 question, --

10:45:22 1 A. That was --

10:45:23 2 MR. GORDON: -- lack of foundation.

10:45:24 3 A. That was unlikely to have clinical
10:45:27 4 significance.

10:45:27 5 Q. Okay. And would it help if there were a
10:45:33 6 study that showed that there was a statistically
10:45:36 7 significant difference in terms of the amount of
10:45:38 8 bacteria produced by the Bair Hugger when it was on
10:45:41 9 versus off?

10:45:43 10 MR. GORDON: Object to the form of the
10:45:44 11 question, lack of foundation, incomplete hypothetical.

10:45:47 12 A. Well I mean statistical significance is
10:45:51 13 not -- well it's -- it's part of what -- what would be
10:45:55 14 convincing, but it also has to do with the magnitude
10:45:58 15 of what that effect would be, of whether or not it
10:46:01 16 would have a clinical -- you know, be clinically
10:46:04 17 important.

10:46:04 18 Q. Statistical significance is not the same as
10:46:07 19 clinical significance; correct?

10:46:08 20 A. Correct.

10:46:09 21 Q. And epidemiology does not hinge on whether a
10:46:13 22 result is statistically significant or not; correct?

10:46:18 23 A. Well the -- the -- for --

10:46:21 24 To definitely demonstrate a -- an
10:46:27 25 epidemiological effect, you'd want the association to

10:46:30 1 be statistically significant. It may not be the only
10:46:33 2 thing you consider, but it's certainly an -- an
10:46:35 3 important part of it.

10:46:35 4 Q. But for clinical significance, it's not
10:46:37 5 necessary to have statistical significance.

10:46:39 6 A. Oh, I -- I'm -- no, I --

10:46:42 7 Q. Not necessary.

10:46:44 8 A. I think it would be important to have
10:46:46 9 statistical significance to say that it's
10:46:49 10 clinically -- clinically important.

10:46:50 11 Q. Do you disagree with the recent statement of
10:46:53 12 The American Statistical Association that concludes
10:46:55 13 that clinical significance is not determined by
10:46:58 14 statistical significance?

10:47:01 15 MR. GORDON: Object to the form of the
10:47:03 16 question.

10:47:08 17 A. I'm not familiar with the particular
10:47:10 18 statement that you're saying, but I mean I think
10:47:12 19 it's -- I think we're, again, quibbling about --

10:47:17 20 I mean I -- I doubt that they're saying
10:47:19 21 that -- that when looking at a clinical effect, you
10:47:24 22 don't -- you're not interested in whether or not the
10:47:26 23 association of the study was statistically
10:47:28 24 significant.

10:47:28 25 Q. Well I'm not -- I'm not limiting the

10:47:31 1 question to whether you're interested in it.

10:47:35 2 Whether something is statistically

10:47:37 3 significant or not is a different question than

10:47:40 4 whether it's clinically significant.

10:47:42 5 A. It is a different question.

10:47:43 6 Q. Okay.

10:47:43 7 A. Yes.

10:47:47 8 Q. Statistical significance is not equivalent

10:47:49 9 to scientific, human, or economic significance;

10:47:52 10 correct?

10:47:52 11 A. Correct.

10:47:52 12 Q. One of the reasons why you say the McGovern

10:47:56 13 study has no import with respect to the relationship

10:47:58 14 between the Bair Hugger and deep joint infection is

10:48:01 15 that, based on using Fisher's exact test instead of

10:48:04 16 chi-squared and based on Albrecht's Exhibit 10, the

10:48:07 17 p-value is .0507; correct?

10:48:09 18 MR. GORDON: Object to the form of the

10:48:11 19 question.

10:48:12 20 A. I think that's what I -- what I found in my

10:48:15 21 analysis, yes.

10:48:16 22 Q. And the statement of the ASA is that

10:48:19 23 statistical significance is not equivalent to

10:48:21 24 scientific, human, or economic significance; correct?

10:48:23 25 A. Yes.

10:48:25 1 MR. SACCHET: Okay. We'll take a break.

10:56:37 2 (Recess taken.)

10:56:37 3 BY MR. SACCHET:

10:56:43 4 Q. Dr. Holford, if we could turn back to your
10:56:47 5 curriculum vitae, which has been marked as Exhibit 2.

10:56:54 6 I don't think you'll need it to answer these

10:56:55 7 questions, but in case you do, there it is.

10:57:02 8 You are a fellow of The American College of
10:57:05 9 Epidemiology; correct?

10:57:07 10 A. Yes.

10:57:08 11 Q. Does your membership in the college reflect
10:57:12 12 your expertise in that subject matter?

10:57:15 13 A. Yes.

10:57:16 14 Q. And that subject matter is the incidence of
10:57:21 15 disease in certain populations; correct?

10:57:25 16 A. Well it's -- it's more than just the
10:57:27 17 incidence, it's the -- it's a -- a lot of studies of
10:57:34 18 etiology of disease.

10:57:35 19 Q. Okay. How many members are there in the
10:57:39 20 college, do you know?

10:57:41 21 A. No, I don't.

10:57:42 22 Q. Okay. The other members are presumably
10:57:44 23 experts in the field as well; correct?

10:57:47 24 A. In different aspects of epidemiology, yes.

10:57:50 25 Q. What does it take for one to become the

10:57:53 1 president of the college?

10:57:56 2 A. You have to run for election and be -- get
10:58:01 3 the most votes.

10:58:02 4 Q. Have you voted in such an election?

10:58:05 5 A. I -- I think I voted, yes.

10:58:08 6 Q. What are your criteria for voting someone to
10:58:10 7 be president?

10:58:13 8 A. My view of their scientific standing.

10:58:20 9 Q. So the president would have sound scientific
10:58:23 10 standing in your view.

10:58:25 11 A. Yes. Oh, yeah.

10:58:27 12 Q. You're aware that Dr. Samet was elected
10:58:29 13 president of the college in 1999; correct?

10:58:32 14 A. Yes.

10:58:34 15 Q. In that regard you review -- you view Dr.
10:58:38 16 Samet as an expert in epidemiology.

10:58:39 17 A. I do.

10:58:40 18 Q. You're also a member of The American College
10:58:43 19 of Statistics; correct?

10:58:45 20 A. Well it's The American Statistical
10:58:48 21 Association.

10:58:48 22 Q. Okay. Thanks for the clarification.

10:58:54 23 And I assume the same holds true: if you're
10:58:55 24 a member of that association, presumably you're an
10:58:59 25 expert in some matter in statistics; correct?

10:59:02 1 A. That's correct.

10:59:03 2 Q. Are you aware that Professor Nachtsheim is
10:59:06 3 also a member of the association?

10:59:08 4 A. I didn't know that, but --

10:59:10 5 Q. You know that Professor Nachtsheim was one
10:59:15 6 of the authors of the McGovern study; correct?

10:59:15 7 A. Yes.

10:59:17 8 Q. So you have no doubt that Professor
10:59:21 9 Nachtsheim is an expert in the field of statistics.

10:59:24 10 A. Yes, I'm sure he'd have some expertise in
10:59:27 11 that.

10:59:33 12 Q. You did not review Professor Nachtsheim's
10:59:38 13 deposition; correct?

10:59:38 14 A. No, I did not.

10:59:43 15 Q. So you do not know anything about Dr.
10:59:48 16 Samet's testimony regarding the statistical methods
10:59:50 17 that were employed in the McGovern study; correct?

10:59:53 18 MR. GORDON: Did you mean to say "Samet?"

10:59:55 19 MR. SACCHET: No.

10:59:56 20 MR. GORDON: You just said "Samet."

10:59:57 21 MR. SACCHET: Oh. Thanks, Mr. Gordon.

10:59:59 22 Q. You're not aware of what Professor
11:00:03 23 Nachtsheim testified about the statistical methods
11:00:06 24 used in the McGovern study; correct?

11:00:09 25 A. I -- I --

11:00:11 1 My knowledge of what was -- statistical
11:00:15 2 methods were used is what's -- is what was in the
11:00:17 3 McGovern paper.

11:00:18 4 Q. So the Nachtsheim deposition transcript
11:00:20 5 played no role in your opinion that you provided in
11:00:23 6 your expert report; correct?

11:00:25 7 A. Correct.

11:00:26 8 Q. You're not aware of whether Professor
11:00:29 9 Nachtsheim provided a justification for using
11:00:31 10 chi-squared instead of Fisher's exact; are you?

11:00:34 11 A. No, I'm not.

11:00:35 12 Q. You're not aware of whether Professor
11:00:38 13 Nachtsheim continues to stand by the calculations
11:00:39 14 that were made in the McGovern study; correct?

11:00:41 15 A. I -- I have no idea what -- what his
11:00:47 16 opinions are.

11:00:47 17 Q. You're not aware of whether Professor
11:00:50 18 Nachtsheim commented on the accuracy of Albrecht
11:00:52 19 Exhibit 10 or McGovern Exhibit 16; correct?

11:00:58 20 A. Correct.

11:01:04 21 Q. I apologize if I've already asked the
11:01:08 22 question, but you did not review the Moretti study in
11:01:14 23 terms of drafting your expert report in this case;
11:01:17 24 correct?

11:01:17 25 A. Correct.

11:01:18 1 Q. Didn't you want to have all of the author
11:01:26 2 testimony when making determinations about the
11:01:27 3 accuracy of the McGovern study?

11:01:29 4 MR. GORDON: Object to the form of the
11:01:30 5 question.

11:01:32 6 A. Yeah. I'm not -- all -- all of their
11:01:40 7 testimony or all of their work --

11:01:41 8 I mean the paper, I think, pretty much
11:01:46 9 stands on -- on -- on its own. It justifies what
11:01:48 10 it -- what it did and why it did it.

11:01:50 11 Q. Well you reviewed the Albrecht testimony as
11:01:53 12 it related to the McGovern study; correct?

11:01:55 13 A. I did -- I did review it, yes.

11:01:57 14 Q. And you relied on that testimony with
11:02:00 15 respect to using Albrecht Exhibit 10 --

11:02:03 16 A. Yes.

11:02:03 17 Q. -- to reanalyze the data; correct?

11:02:05 18 A. Yes. Well that's -- that's correct.

11:02:07 19 Q. And you also reviewed Mr. McGovern's
11:02:09 20 testimony; did you?

11:02:10 21 A. Yes.

11:02:10 22 Q. Did you review both days of testimony?

11:02:14 23 A. I believe I did, yes.

11:02:16 24 Q. And you reviewed Mr. Reed's testimony as
11:02:18 25 well.

11:02:18 1 A. Yes.

11:02:19 2 Q. Why did you not review Professor

11:02:21 3 Nachtsheim's testimony?

11:02:23 4 A. I don't know that I --

11:02:28 5 I just don't -- don't -- don't recall that.

11:02:30 6 I -- yeah.

11:02:30 7 Q. He's the only professor of statistics that

11:02:34 8 was an author of that study; correct?

11:02:36 9 A. Apparently, yes.

11:02:38 10 Q. Don't you think it would have been helpful

11:02:39 11 to review that deposition considering that you

11:02:43 12 reviewed the other authors' deposition testimony?

11:02:45 13 MR. GORDON: Object to the form of the

11:02:46 14 question.

11:02:50 15 A. It -- it -- it could have been helpful, but

11:02:53 16 I -- I think what --

11:02:54 17 The statistical methods that were used were

11:02:57 18 pretty well described in the paper.

11:02:59 19 Q. But you're not aware of the justifications

11:03:01 20 for why particular methods were used according to

11:03:06 21 Professor Nachtsheim; correct?

11:03:06 22 A. I'm not sure what justifications he used,

11:03:08 23 but they are commonly-used statistical methods that

11:03:16 24 were in that paper, and so I'm -- I would not be --

11:03:23 25 You know, it -- it's -- it -- it's fairly

11:03:26 1 common to use, I mean, basically use chi-square.

11:03:29 2 Q. One of your issues with the study is it used
11:03:33 3 chi-squared instead of Fisher's exact; correct?

11:03:36 4 A. In this particular --

11:03:37 5 Yes.

11:03:37 6 Q. And you're not aware of perhaps why
11:03:39 7 Professor Nachtsheim decided to use chi-squared
11:03:43 8 instead of Fisher's exact.

11:03:45 9 A. Instead of Fish --

11:03:45 10 No, I'm not -- I don't -- I don't see why I
11:03:47 11 would not -- if he --

11:03:48 12 Whatever reasoning he might have had, I
11:03:50 13 would -- I would dispute that for reasons that are in
11:03:54 14 my report.

11:03:55 15 Q. And you've already said that Professor
11:03:58 16 Nachtsheim is an expert in statistics because he is a
11:04:00 17 member of The American Statistical Association;
11:04:03 18 correct?

11:04:03 19 A. He -- he is an expert. He -- he obviously
11:04:07 20 has interest in -- in statistics, --

11:04:10 21 Q. Okay.

11:04:10 22 A. -- but --

11:04:11 23 Q. Did you ask for Professor Nachtsheim's
11:04:14 24 deposition?

11:04:15 25 A. No, I didn't.

11:04:17 1 Q. Were the other deposition transcripts from
11:04:21 2 Mr. Albrecht, Mr. McGovern and Mr. Reed provided to
11:04:24 3 you?

11:04:24 4 A. Yes.

11:04:25 5 Q. And Professor Nachtsheim's deposition was
11:04:29 6 not provided to you.

11:04:30 7 A. I don't recall that it was. I -- it may
11:04:34 8 have been, I -- I just -- I'm -- I just don't recall
11:04:40 9 it.

11:04:40 10 Q. I'm going to put down the guard. I mean
11:04:43 11 don't -- don't you find that unusual, that three of
11:04:44 12 the authors' deposition transcripts were provided to
11:04:47 13 you but the only statistician's deposition transcript
11:04:50 14 was not?

11:04:51 15 MR. GORDON: Object to the form of the
11:04:52 16 question.

11:04:54 17 A. These -- yeah, I mean I -- I was --

11:04:57 18 The statistical aspects of this study are
11:05:01 19 not terribly complicated, frankly.

11:05:05 20 Q. You take issue, though, with respect to the
11:05:07 21 tabulation of the data; correct?

11:05:10 22 A. Oh, it's -- you --

11:05:12 23 It's important that you put the right
11:05:13 24 numbers down, yeah.

11:05:15 25 Q. And Professor Nachtsheim could have opined

11:05:18 1 on the tabulation of the data; correct?

11:05:22 2 MR. GORDON: Object to the form of the
11:05:23 3 question.

11:05:24 4 A. I -- I suppose he might have. I mean the
11:05:28 5 other -- the other authors certainly did.

11:05:28 6 Q. And that's why you reviewed their deposition
11:05:30 7 testimony; correct?

11:05:30 8 A. That's -- that's part of what I -- what I --
11:05:33 9 what came out of my review of their testimony, yes.

11:05:40 10 Q. Is --

11:05:43 11 So everything that's been marked on page 14
11:05:45 12 of your report, in addition to the recent Augustine
11:05:50 13 study, are the materials that you reviewed in drafting
11:05:54 14 your report and providing testimony today.

11:05:58 15 A. Well the recent August -- Augustine study I
11:06:03 16 saw after --

11:06:04 17 Q. Yes.

11:06:04 18 A. -- this was submitted, so that's not on here
11:06:08 19 because I -- I hadn't seen it when I wrote this.

11:06:09 20 Q. But that's the totality of evidence up to
11:06:12 21 this point in time.

11:06:13 22 A. That's pretty much it, yes. Yes.

11:06:13 23 MR. GORDON: I -- I think he also reviewed
11:06:14 24 the Samet testimony about the Augustine article.

11:06:17 25 THE WITNESS: Oh, I'm sorry, yes.

1 MR. SACCHET: Okay.

11:06:19 2 THE WITNESS: There was also that.

11:06:19 3 Q. Okay. So no other articles other than

11:06:22 4 what's been listed on page 14.

11:06:25 5 A. No.

11:06:26 6 Q. And no other deposition transcripts aside

11:06:29 7 from Samet and I think you said Augustine.

11:06:32 8 A. I saw -- I saw just a couple of pages of --

11:06:36 9 of Augustine, but --

11:06:37 10 Q. Okay. Did you perform any independent

11:06:40 11 investigation outside of what was provided to you?

11:06:43 12 A. No.

11:06:47 13 Q. So everything that you're relying on is what

11:06:52 14 3M provided to you.

11:06:52 15 A. That's correct.

11:06:57 16 Q. Okay. With respect to the McGovern study,

11:07:00 17 I'd like to review that quickly. I assume that we are

11:07:08 18 on the same page, doctor, with calling this study "the

11:07:11 19 McGovern study," which is the one that you discuss in

11:07:13 20 your report; correct?

11:07:14 21 A. Yes.

11:07:21 22 (Exhibit 13 was marked for

11:07:23 23 identification.)

11:07:23 24 BY MR. SACCHET:

11:07:27 25 Q. We have handed you what has been marked as

11:07:29 1 Exhibit 13. The title is "Forced-air warming and
11:07:34 2 ultra-clean ventilation do not mix" by McGovern et al;
11:07:38 3 correct?

11:07:38 4 A. Correct.

11:07:39 5 Q. I do not know whether you will need the
11:07:41 6 study to answer these questions, but feel free to
11:07:44 7 refer to it as you see fit.

11:07:46 8 There were two components to this study;
11:07:48 9 correct?

11:07:48 10 A. That's correct.

11:07:50 11 Q. There was a study of bubbles in an
11:07:54 12 experimental setting, and then there was the
11:07:56 13 observational data aspect of the study; correct?

11:07:59 14 A. Yes.

11:08:00 15 Q. And the first part of the study, which we've
11:08:03 16 discussed a little bit, found a significant increase
11:08:06 17 in the amount of bubbles over the surgical site in
11:08:09 18 this experimental study when the Bair Hugger was used
11:08:11 19 compared to a conductive warming device; correct?

11:08:14 20 A. That's what they report, yes.

11:08:15 21 Q. Okay. And the second part, which involved
11:08:18 22 the observational data set, involved 1,437 patients;
11:08:25 23 correct?

11:08:25 24 A. I think that's right.

11:08:26 25 Q. Table II, you might have to do a little

11:08:32 1 math, --

11:08:33 2 A. Yeah.

11:08:33 3 Q. -- or I believe on page 1541 you'll see it

11:08:36 4 in the bottom left-hand corner.

11:08:41 5 A. Yeah. Okay.

11:08:52 6 Yeah, 1066 and 371 are the two groups.

11:08:55 7 Q. Which adds up though 1437.

11:08:57 8 A. Okay. Yeah, right.

11:08:58 9 Q. And the -- the study period was 2.5 years;

11:09:04 10 correct?

11:09:04 11 A. I think that's right, yes.

11:09:06 12 Q. You can look at page 1540 --

11:09:08 13 A. Yeah.

11:09:09 14 Q. -- on the left-hand side under "Joint

11:09:10 15 Infection data."

11:09:11 16 A. Right.

11:09:12 17 Q. And deep joint infections as opposed to

11:09:17 18 superficial or wound infections was the outcome of

11:09:19 19 interest; correct?

11:09:20 20 A. That's correct.

11:09:21 21 Q. And there were three warming phases, there

11:09:23 22 was the Bair Hugger period, a transitional period, and

11:09:26 23 a conductive warming period; correct?

11:09:28 24 A. That's correct.

11:09:29 25 Q. And during the Bair Hugger period there was

11:09:32 1 a change in the antibiotic; correct?

11:09:35 2 A. That's correct.

11:09:35 3 Q. The first antibiotic was Gentamicin;

11:09:39 4 correct?

11:09:39 5 A. Yes.

11:09:39 6 Q. And the second antibiotic was Gentamicin

11:09:44 7 plus Teicoplanin.

11:09:46 8 A. That's correct.

11:09:47 9 Q. Are you comfortable referring to that

11:09:50 10 protocol as GenTeic?

11:09:50 11 A. Okay.

11:09:51 12 Q. There was also a change in the

11:09:53 13 thromboprophylaxis.

11:09:55 14 A. That's right.

11:09:56 15 Q. The first thromboprophylaxis was tinzaparin

11:10:00 16 during the Bair Hugger arm of the study; correct?

11:10:03 17 A. Yes.

11:10:03 18 Q. And in the last six months of the Bair

11:10:04 19 Hugger arm there was a change to rivaroxaban; correct?

11:10:08 20 A. That's correct.

11:10:08 21 Q. Are you okay with referring to rivaroxaban

11:10:12 22 as Xarelto?

11:10:14 23 A. Okay.

11:10:14 24 Q. It's just the pharmaceutical name of -- of

11:10:16 25 that thrombo.

11:10:17 1 And in the Hot Dog period patients went back
11:10:21 2 and received tinzaparin as opposed to Xarelto;
11:10:25 3 correct?

11:10:25 4 A. That's correct.

11:10:26 5 Q. Okay. So results reported in Table II of
11:10:29 6 this study show that three out of 371 patients
11:10:34 7 developed a deep joint infection in 60 days; correct?

11:10:37 8 A. That's correct.

11:10:37 9 Q. And the percentage of that infection rate is
11:10:41 10 .8 percent; correct?

11:10:41 11 A. Correct.

11:10:42 12 Q. As also reported in Table II, 32 out of
11:10:48 13 1,066 patients developed a deep joint infection after
11:10:53 14 receiving the Bair Hugger warming; correct?

11:10:55 15 A. That's correct.

11:10:58 16 Q. The change from the infection rate of the
11:11:02 17 Bair Hugger --

11:11:03 18 Which is three percent; correct?

11:11:04 19 A. Yes.

11:11:05 20 Q. -- to the .8 percent is a marked decline; is
11:11:09 21 it not?

11:11:09 22 MR. GORDON: Object to the form of the
11:11:10 23 question.

11:11:13 24 A. It -- it is -- it is lower, yes.

11:11:17 25 Q. Would you agree that it's a marked decline?

11:11:19 1 MR. GORDON: Object to the form of the
11:11:21 2 question.

11:11:22 3 A. I don't under -- what do you mean by --
11:11:24 4 What is "marked?"

11:11:25 5 Q. Have you asked Dr. Borak?

11:11:29 6 A. The meaning of --

11:11:31 7 It's -- it's not a quantitative term that
11:11:33 8 I'm familiar with.

11:11:34 9 Q. So to the extent that Dr. Borak used that
11:11:37 10 language in his report, you wouldn't feel comfortable
11:11:39 11 with the same language.

11:11:40 12 A. I'm not fam --

11:11:42 13 I have not read his report. I mean it's
11:11:47 14 a -- it's a -- it's a -- it's a substantial -- it's a
11:11:52 15 big decline, yes.

11:11:53 16 Q. A big decline.

11:11:55 17 A. It is a big difference.

11:12:03 18 Q. And the p-value reported in Table II is
11:12:08 19 .024; correct?

11:12:10 20 A. That's -- that is the reported value, yes.

11:12:12 21 Q. And that reported p-value is statistically
11:12:15 22 significant based on the 95 percent confidential
11:12:17 23 interval; correct?

11:12:19 24 A. I would disagree with your language.

11:12:23 25 Q. Okay. It's maybe not meaningful. I

11:12:24 1 apologize.

11:12:26 2 A. Yeah. It -- it -- it is significant at the
11:12:27 3 five percent level, yes.

11:12:29 4 Q. Okay. So I always say this wrong, but
11:12:31 5 perhaps you can edify me. If you have a statistically
11:12:34 6 significant p-value using a 95 percent or five -- five
11:12:40 7 percent threshold, --

11:12:42 8 A. Yes.

11:12:42 9 Q. -- does that mean that if you repeated the
11:12:45 10 study a hundred times using the same -- a similar
11:12:49 11 population of patients, that you would expect the same
11:12:52 12 outcome at least 95 -- 95 times out of a hundred?

11:12:56 13 A. No.

11:12:56 14 Q. Okay. What --

11:12:57 15 So please edify.

11:13:01 16 A. What that means is if -- if there is no
11:13:05 17 association and you repeat the study, you're comparing
11:13:16 18 two groups where there is no effect, then just five
11:13:22 19 percent of the time you will reject the -- you will
11:13:25 20 reject the -- the null hypothesis, which is that there
11:13:29 21 is no effect.

11:13:30 22 Q. Okay. So is another way to think about it
11:13:34 23 is there's a five-percent chance of getting a false
11:13:37 24 positive?

11:13:40 25 A. No, it's not looking at the false positive.

11:13:44 1 Q. Okay.

11:13:44 2 A. It's looking at what's the -- what's the
11:13:46 3 chance that you would see this big of a difference if
11:13:49 4 there was no effect.

11:13:50 5 Q. Okay. Got it.

11:13:51 6 A. And it's only five per --
11:13:52 7 It's less than five percent, --

11:13:55 8 Q. Got it.

11:13:55 9 A. -- so that's a fairly rare event. So we're
11:13:57 10 doing this under the null hypothesis, --

11:13:59 11 Q. Yup.

11:14:00 12 A. -- so therefore we would reject that
11:14:03 13 hypothesis --

11:14:03 14 Q. Yeah.

11:14:04 15 A. -- and take the alternative.

11:14:05 16 Q. Got it.

11:14:06 17 A. Yeah.

11:14:07 18 Q. And the odds ratio reported in Table II is
11:14:10 19 3.8; correct?

11:14:11 20 A. Yes, I think that's correct.

11:14:13 21 Q. And would you agree with Dr. Borak's
11:14:15 22 statement that that's a significantly increased odds
11:14:19 23 ratio?

11:14:20 24 A. Well there are two -- two parts to that.
11:14:25 25 It -- it is statis -- using the approach reported, it

11:14:31 1 is statistically significant. The other part of it is
11:14:35 2 what is the magnitude of that effect, and for the
11:14:37 3 magnitude, of course, the point estimate is 3.8, which
11:14:41 4 is a fairly large effect. The -- the confidence
11:14:45 5 interval on the other hand, as they reported here, is
11:14:50 6 1.2 to 12.5, so it's a very broad -- it's over the
11:14:56 7 line of statistical significance, but the precision
11:14:59 8 is --

11:15:01 9 Well I mean this is a tenfold range for your
11:15:03 10 95 percent confidence interval for the -- for -- for
11:15:06 11 your estimate of what that effect is.

11:15:08 12 Q. And I'll get to the confidence interval
11:15:10 13 later on this afternoon, but with respect to just the
11:15:12 14 odds ratio --

11:15:14 15 A. Oh, sure.

11:15:15 16 Q. -- of 3.8, do you agree with Dr. Borak that
11:15:18 17 it significantly increased OR.

11:15:21 18 A. Yes.

11:15:22 19 Q. Significantly increased.

11:15:25 20 A. It's increased, yeah.

11:15:27 21 Q. Okay. On page two of your report you
11:15:31 22 provide a calculation that uses different infection
11:15:40 23 data than what was reported in the McGovern study;
11:15:45 24 correct?

11:15:45 25 A. It's different from what's in the paper,

11:15:47 1 yes.

11:15:48 2 Q. So instead of using three Hot Dog infections
11:15:52 3 as reported in the study, your tabulation uses four
11:15:57 4 Hot Dog infections; correct?

11:15:59 5 A. We found the four based on the data in --
11:16:03 6 well, it's Exhibit -- it's Exhibit 10 of --

11:16:09 7 Q. Mr. Albrecht.

11:16:10 8 A. -- Albrecht's and also, I mean, there's
11:16:13 9 related data on that that McGovern provided and -- and
11:16:17 10 whatnot.

11:16:17 11 Q. Okay.

11:16:18 12 A. So going back to the -- the raw data,
11:16:20 13 that -- that -- that is the basis of what I report on
11:16:25 14 page two.

11:16:25 15 Q. And you also in that calculation used 31
11:16:31 16 Bair Hugger infections as opposed to the 32 that was
11:16:34 17 reported in the study; correct?

11:16:37 18 A. That's -- that's correct, yeah.

11:16:39 19 Q. And that's --

11:16:40 20 A. It seems like in that data set there's one
11:16:43 21 observation that occurred during the Hot Dog period
11:16:53 22 that was attributed in the McGovern tabulation to
11:16:59 23 being a -- a Bair Hugger infection when it actually
11:17:03 24 occurred during the Hot Dog period, so it -- based on
11:17:08 25 their description of what the -- what the study was,

11:17:10 1 it should have been calculated -- attributed to -- to
11:17:14 2 that treatment.

11:17:15 3 Q. So you said it seems that. You're not sure
11:17:17 4 though; right?

11:17:17 5 A. Well it's --

11:17:19 6 Taking those dates, doing what they said the
11:17:22 7 study was, that's what you get.

11:17:24 8 Q. Okay.

11:17:24 9 A. That's -- that's what I report in here.

11:17:26 10 Q. But you would agree that the data in your
11:17:28 11 report in terms of how many infections were in each
11:17:32 12 arm of the study is different than what --

11:17:34 13 A. That's correct.

11:17:35 14 Q. -- the author published; correct?

11:17:36 15 A. That's correct.

11:17:37 16 Q. And you just mentioned that with respect to
11:17:39 17 conducting that calculation of the incidence of
11:17:43 18 infection in those Bair Hugger patients and Hot Dog
11:17:46 19 patients, you relied on Albrecht Exhibit 10; correct?

11:17:49 20 A. Yes.

11:17:50 21 MR. GORDON: Object to the form of the
11:17:51 22 question. Misstates his testimony.

11:18:04 23 (Exhibit 14 was marked for
11:18:05 24 identification.)

11:18:05 25 BY MR. SACCHET:

11:18:08 1 Q. I understand that there's a lot of pages in
11:18:11 2 front of you, but does this appear to be the document
11:18:17 3 that you reviewed in determining that there were,
11:18:21 4 according to you, one more infection in the Hot Dog
11:18:24 5 group and one less in the Bair Hugger group?

11:18:37 6 A. It -- it -- it appears to be, yes.

11:18:38 7 Q. And this document was provided to you by 3M?

11:18:42 8 A. Yes.

11:18:43 9 Q. Okay. As kind of just a general statistical
11:18:50 10 or epidemiological matter, you need to rely on
11:18:54 11 complete data sets; correct?

11:18:56 12 A. Yes.

11:18:57 13 Q. And if you don't rely on complete data sets,
11:19:00 14 there could be an artifact issue; correct?

11:19:07 15 A. Well -- well there could be -- there could
11:19:11 16 be an error in the calculation that is worth checking.

11:19:15 17 Q. And that would be an artifact; right?

11:19:17 18 A. Okay. Yeah.

11:19:19 19 Q. Could you please turn to the Bates number
11:19:23 20 AUGUSTINE -- which they all share in common -- 5277
11:19:30 21 in the document.

22 MR. GORDON: And the system.

11:19:32 23 MR. SACCHET: Oh, so I can back up.

11:19:33 24 Q. Are you familiar with Bates numbers, doctor?

11:19:36 25 A. The base numbers? No, I'm not sure which

11:19:38 1 ones you're talking about.

11:19:38 2 Q. The Bates number is the number on the bottom
11:19:41 3 of the page.

11:19:41 4 MR. GORDON: Did you say 5277?

11:19:43 5 MR. SACCHET: Yes.

11:19:43 6 MR. GORDON: My copy doesn't have one.

11:19:45 7 MR. SACCHET: Does yours?

11:19:48 8 THE WITNESS: No.

11:19:49 9 MR. SACCHET: Mine doesn't either.

11:19:52 10 Q. Do you know whether the copy that you had
11:19:54 11 had that page?

11:19:58 12 A. I assumed it was all there, yeah. I
11:20:02 13 didn't --

11:20:02 14 Q. Well --

11:20:03 15 A. Yeah, I don't -- don't recall.

11:20:05 16 Q. Yeah. You didn't look at whether there was
11:20:07 17 a gap in the Bates numbers that were included on the
11:20:09 18 pages; did you?

11:20:10 19 A. No, I didn't.

11:20:11 20 Q. Okay. I'm going to try to walk you through
11:20:14 21 the sequence in -- of pages here. On 5278 do you see
11:20:18 22 the table?

11:20:19 23 A. Yes.

11:20:19 24 Q. And that table has a list of dates in column
11:20:24 25 G?

11:20:26 1 A. Correct.

11:20:26 2 Q. Okay. And then the second page is another
11:20:27 3 large table of -- mostly ends in no quantitative data;
11:20:32 4 correct?

11:20:32 5 A. Yes.

11:20:33 6 Q. And then the third page is a similar table,
11:20:36 7 but it has kind of these -- a bunch of Ns with null
11:20:40 8 values.

11:20:41 9 A. Correct.

11:20:41 10 Q. Okay. The fourth page is also a large table
11:20:44 11 with virtually no data on it.

11:20:47 12 A. Correct.

11:20:49 13 Q. And the fourth page is a much narrower table
11:20:52 14 that, in this instance, documents what appears to be a
11:20:56 15 deep joint infection; correct?

11:20:57 16 MR. GORDON: You mean the fifth page?

11:20:58 17 MR. SACCHET: The fifth page. Thank you,
11:21:00 18 Mr. Gordon.

11:21:01 19 A. Correct.

11:21:01 20 Q. And that page in particular is AUGUSTINE_
11:21:05 21 0005282; correct?

11:21:08 22 A. AUGUSTINE --

11:21:09 23 Q. At the bottom.

11:21:10 24 A. Oh, I'm sorry. Yes.

11:21:11 25 Q. Okay. Let's turn to the next page and see

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11:21:15 1 if the pattern repeats itself of those five pages. Is
11:21:18 2 the first page a table with a bunch of dates and other
11:21:22 3 values?
11:21:22 4 A. Yes.
11:21:23 5 Q. Is the second table one with a bunch of Ns?
11:21:26 6 A. Yes.
11:21:27 7 Q. Is the third page, with the AUGUSTINE Bates
11:21:32 8 number 005285, a table with null values?
11:21:39 9 A. Yeah, mostly null -- N and null. Yeah.
11:21:42 10 Q. Yeah. Is the fourth page, which has the
11:21:45 11 Bates number AUGUSTINE_0005286, largely a blank table?
11:21:50 12 A. Yes.
11:21:50 13 Q. And is the fifth page, marked as AUGUSTINE_
11:21:55 14 005287, a narrower table that has NOs and in one
11:22:02 15 instance a YES?
11:22:03 16 A. Yes.
11:22:03 17 Q. Okay. I'll represent to you that this
11:22:07 18 pattern runs true through the document itself.
11:22:10 19 A. Yes.
11:22:10 20 Q. But if we could turn back to Bates number
11:22:14 21 AUGUSTINE_005278, --
11:22:17 22 A. 5278. Okay.
11:22:21 23 Q. -- and the missing page that we don't have
11:22:23 24 is AUGUSTINE_005277; correct?
11:22:26 25 A. Correct.

11:22:27 1 Q. Okay. So let's flip to AUGUSTINE_005274,
11:22:35 2 which is three pages before the document.
11:22:38 3 A. Okay.
11:22:41 4 Q. And, excuse me, let's actually go to 5273,
11:22:44 5 the page before that. That's the table like the other
11:22:52 6 pages we've seen that has the dates; correct?
11:22:54 7 A. Correct.
11:22:55 8 Q. On 5273; correct?
11:22:58 9 A. Yes.
11:22:58 10 Q. And then on 5274 we've got the big table
11:23:03 11 with a bunch of Ns; correct?
11:23:07 12 A. Correct.
11:23:09 13 Q. And the third page, which is 5275, there are
11:23:11 14 kind of the null values and other Ns; right?
11:23:14 15 A. Yes.
11:23:14 16 Q. Following the same pattern as the other
11:23:16 17 pages we've established; correct?
11:23:17 18 A. Correct.
11:23:18 19 Q. And the fourth page is, like the other
11:23:21 20 fourth pages in other sequences, a big table with
11:23:26 21 bunches of zeroes; right?
11:23:28 22 A. Bunch of blanks.
11:23:29 23 Q. Yeah.
24 A. Yeah, uh-huh.
11:23:29 25 Q. And that's like the fourth page in the other

11:23:31 1 sequences we went over; correct?

11:23:32 2 A. Correct.

11:23:33 3 Q. The page that's missing, 5278, is the narrow
11:23:36 4 table; correct?

11:23:37 5 MR. GORDON: 5277 you mean?

11:23:39 6 MR. SACCHET: 5277. I apologize.

11:23:41 7 A. That's right.

11:23:41 8 Q. And based on the sequence in the other
11:23:43 9 documents we looked at, that is the table that has
11:23:45 10 information as to whether or not there was a deep
11:23:46 11 joint infection; correct?

11:23:47 12 A. Correct.

11:23:48 13 Q. So this document that you relied on in your
11:23:50 14 report was missing the page that had information as to
11:23:56 15 whether or not there was a deep joint infection in the
11:23:58 16 time period that describes these five pages in the
11:24:01 17 table.

11:24:03 18 A. I --

11:24:05 19 As I -- as I said, I don't -- I don't recall
11:24:07 20 going over all of the -- the details in these pages
11:24:11 21 and seeing that that was missing.

11:24:12 22 Q. So you weren't aware that there was the
11:24:13 23 missing page that included infection data regarding
11:24:16 24 the use of the Bair Hugger device; correct?

11:24:18 25 MR. GORDON: Object to the form of the

11:24:20 1 question, assumes facts not in evidence.

11:24:21 2 A. I didn't see that there was a -- a -- a -- a
11:24:29 3 miss -- a missing page in the -- in the -- the data
11:24:32 4 set that I used to analyze.

11:24:34 5 Q. Let's go to AUGUSTINE_5273, which was the
11:24:37 6 first page of the sequence.

11:24:38 7 A. Right.

11:24:39 8 Q. The dates that are delineated there are from
11:24:42 9 September 2008 to September 26, 2008; correct?

11:24:48 10 A. September 8, yeah, twenty --
11:24:50 11 Yeah, uh-huh.

11:24:51 12 Q. And the Bair Hugger period of this study of
11:24:53 13 the McGovern et al paper began in July of 2008;
11:24:58 14 correct?

11:24:58 15 A. Yes.

11:24:59 16 Q. And it ran until February of 2010; correct?

11:25:01 17 A. Yes.

11:25:03 18 Q. So this table describes operations that
11:25:08 19 occurred when using the Bair Hugger in the McGovern
11:25:11 20 study; correct?

11:25:11 21 A. Correct.

11:25:12 22 Q. So if there were an infection that would
11:25:14 23 have occurred in this time period, it would have been
11:25:18 24 during the Bair Hugger warming period; correct?

11:25:21 25 A. Yes.

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11:25:22 1 Q. And we're missing the page in this document
11:25:25 2 to know whether or not there were additional
11:25:28 3 infections in the Bair Hugger period; correct?

11:25:31 4 A. That --

11:25:33 5 Well, that's not in this document, yes. But
11:25:37 6 in the file I --

11:25:39 7 I mean the numbers on my page two
11:25:48 8 essentially correspond to the numbers that are in
11:25:51 9 McGovern's paper, so the results I'm getting from my
11:25:54 10 tabulation, with the one difference of switching the
11:26:00 11 single value -- and if you go to the -- I think it's
11:26:06 12 the -- one of the exhibits from the McGovern
11:26:15 13 testimony, you can -- you can see where that one
11:26:18 14 observation was -- was described as FAW when it should
11:26:29 15 have been -- what is -- CFW or -- yeah.

11:26:31 16 Q. And we'll get to the McGovern exhibit in a
11:26:34 17 couple minutes, --

11:26:35 18 A. Yeah.

11:26:35 19 Q. -- but --

11:26:36 20 A. So we do not -- there's --

11:26:38 21 The numbers that we're ending up with
11:26:40 22 correspond to what is in the McGovern paper.

11:26:43 23 Q. So are you saying you don't feel comfortable
11:26:45 24 relying on Albrecht Exhibit 10?

11:26:48 25 A. Well --

11:26:48 1 MR. GORDON: Object to the form of the
11:26:50 2 question.

11:26:50 3 A. The -- the data that we're looking at are
11:26:54 4 derived from -- are basically from -- from --
11:26:58 5 from -- from -- from this, and I'm -- it's based on a
11:27:01 6 table from this that I am doing in my analysis.

11:27:04 7 Q. And we're missing a page that deals with the
11:27:08 8 presence or not of deep joint infection; correct?

11:27:11 9 A. The -- the data file that I -- that I'm
11:27:14 10 using is these same data that -- that are -- that I
11:27:18 11 think are tabulated in this. They're tabulated here.
11:27:23 12 Apparently, one of the pages got missed in -- when
11:27:28 13 they produced -- produced this. I wasn't -- and I --
11:27:34 14 you know, I wasn't shuffling through by hand
11:27:39 15 everything here to -- to do the -- to do the
11:27:41 16 tabulation.

11:27:42 17 Q. So are you relying on McGovern 16 instead of
11:27:45 18 this?

11:27:45 19 A. No. Because McGovern 16, it includes
11:27:53 20 additional detail that -- that corroborate the
11:28:00 21 tabulations that were derived from this -- from this
11:28:05 22 data set.

11:28:09 23 Q. You're aware that this data set was not
11:28:12 24 produced by any authors in the study; correct?

11:28:15 25 MR. GORDON: Object to the form of the

11:28:16 1 question, lack of foundation, assumes facts not in
11:28:20 2 evidence.

11:28:22 3 A. I -- I don't -- I don't know who
11:28:25 4 ultimately -- you know, originally produced this.

11:28:29 5 Q. Why does your report on page two say that it
11:28:35 6 was produced by Dr. Scott Augustine in response to a
11:28:37 7 subpoena? Did you write that?

11:28:39 8 A. I -- I did write that. I --
11:28:41 9 That was my understanding of where the --
11:28:43 10 where the file came from.

11:28:44 11 Q. Dr. Augustine is not an author of the
11:28:46 12 McGovern study; is he?

11:28:47 13 MR. GORDON: Object to the form of the
11:28:48 14 question, lack of foundation, assumes facts not in
11:28:50 15 evidence.

11:28:51 16 A. He's not listed as an author.

11:28:54 17 Q. His --

11:28:55 18 A. My understanding is that he had some
11:28:59 19 involvement with -- with this. And I mean his name's
11:29:03 20 at the bottom of this -- of this document that you
11:29:06 21 just gave me.

11:29:08 22 Q. So do you feel comfortable relying on
11:29:11 23 documents produced by Dr. Augustine?

11:29:14 24 MR. GORDON: Object to the form of the
11:29:18 25 question.

11:29:19 1 A. I don't -- don't re --

11:29:22 2 I -- I'm not -- I'm not sure I understand
11:29:23 3 what you're -- what you're asking.

11:29:25 4 Q. Well you just told me that this is produced
11:29:27 5 by Augustine and you're relying on Exhibit 10.

11:29:32 6 A. I mean Augustine's name is on it.

11:29:34 7 Q. Okay.

11:29:34 8 A. I don't know that he sat there in front of
11:29:37 9 the computer and produced it.

11:29:38 10 Q. So when you say it was produced by Dr. Scott
11:29:41 11 Augustine in response to a subpoena, you don't know
11:29:42 12 whether that's right or wrong.

11:29:44 13 A. I -- I'm basing this on -- on what I
11:29:47 14 understand -- what the -- what -- what I was given to
11:29:50 15 understand of where the data came from that I was
11:29:52 16 using in my analysis.

11:29:53 17 Q. Who gave you that understanding?

11:29:54 18 A. When I was talking to the people that --
11:29:58 19 with 3M.

11:30:00 20 Q. So you relied on 3M's statement that this
11:30:02 21 was produced by Dr. Augustine and you accepted that
11:30:04 22 statement.

11:30:05 23 A. Yes, correct.

11:30:06 24 Q. Did you perform any independent research to
11:30:09 25 determine whether that was true or false?

11:30:09 1 A. No, I didn't.

11:30:11 2 Q. Do you know whether or not Augustine was
11:30:13 3 responsible for collecting the data that was
11:30:15 4 eventually used in the McGovern study?

11:30:20 5 A. I don't know that he did. I -- I'm sure he
11:30:26 6 delegated that to someone, it must be in all
11:30:30 7 likelihood, but I really don't know how this was --
11:30:33 8 was -- who all as involved with producing it.

11:30:36 9 Q. You don't know that Dr. Reed, an orthopedic
11:30:41 10 consultant in the U.K., was the individual responsible
11:30:43 11 for collecting the data?

11:30:45 12 A. I know that Dr. Reed was involved with it.
11:30:49 13 The -- the management organization of that is -- is --
11:30:54 14 is something I don't know.

11:30:57 15 Q. Would knowing that Dr. Reed was in charge of
11:31:01 16 collecting the data instead of Dr. Augustine give you
11:31:04 17 any pause as to whether this is the final data set?

11:31:07 18 MR. GORDON: Object to the form of the
11:31:08 19 question.

11:31:14 20 A. I have --

11:31:16 21 I mean if -- if Dr. Reed produced it and --
11:31:20 22 and Dr. Augustine supplied it, I -- I'm taking the
11:31:25 23 values as they are. I mean I -- I was just analyzing
11:31:29 24 the data that I was -- that I was shown.

11:31:31 25 Q. Has anyone ever asked you for data based on

11:31:34 1 a published cit -- an article that you published?

11:31:36 2 A. Yes.

11:31:36 3 Q. And did you provide the data?

11:31:42 4 A. Very often it's -- I'm --

11:31:44 5 I'm often collaborating with another

11:31:47 6 investigator, so -- so the -- I would usually go to --

11:31:55 7 go to the co-author who owned the data set and they

11:31:58 8 would be involved with the decision on whether or not

11:32:00 9 to provide it.

11:32:01 10 Q. You'd go to a co-author.

11:32:03 11 A. Yes. Well it's often the main author of

11:32:06 12 the -- of the paper.

11:32:07 13 Q. Reed was an author of the --

11:32:09 14 A. Yes.

11:32:11 15 Q. -- of the article; right?

11:32:11 16 A. That's right, he was the senior author.

11:32:13 17 Q. Did you do any investigation to determine

11:32:14 18 whether Mr. Reed produced a data set?

11:32:16 19 A. No, I didn't.

11:32:17 20 Q. So you don't know whether or not Mr. Reed

11:32:19 21 produced the data set as an author of the study that

11:32:22 22 corroborates the data noted in the McGovern study.

11:32:25 23 A. I don't -- don't know that the -- that

11:32:28 24 the -- that -- that that's what -- what transpired.

11:32:34 25 Q. You didn't attempt to determine that though.

11:32:35 1 A. No, I didn't.

11:32:37 2 Q. And you agree with me that Augustine is not
11:32:41 3 a noted author on the study; correct?

11:32:44 4 A. He is not. He is not listed as an author,
11:32:45 5 yes.

11:32:45 6 Q. So you relied on a third party's production
11:32:48 7 of a data set with respect to the McGovern study.

11:32:52 8 A. Well while he's not an author, I don't know
11:32:55 9 if he was involved in fact.

11:32:58 10 Q. So you don't know whether he was involved,
11:33:00 11 but you still relied on his data set.

11:33:03 12 A. Well he had some involvement with -- with
11:33:06 13 this -- with this group. I think --

11:33:08 14 Q. Does it say that on the study?

11:33:09 15 A. I mean where --

11:33:10 16 I forget where the funding comes from.

11:33:12 17 Q. The last page of the study will tell you if
11:33:14 18 there were any benefits. The very last page, very
11:33:17 19 last page. Anything say Augustine?

11:33:31 20 A. I don't think --

11:33:32 21 I don't see anything that says Augustine,
11:33:34 22 I -- but that was not the point that I was -- was
11:33:41 23 making. I'm not sure where the funding for this work
11:33:45 24 came from.

11:33:47 25 Q. So you have no basis to know whether or not

11:33:49 1 the funding came from Augustine; correct?

11:33:54 2 A. Well as I say, I --

11:33:58 3 Oh, I don't know.

11:34:03 4 Q. I'll represent to you that there's no

11:34:04 5 mention of Augustine in the McGovern study. You're

11:34:08 6 not going to find it.

11:34:08 7 A. There -- there is -- there is not. I -- I

11:34:10 8 have acknowledged that there's no -- there's no

11:34:14 9 specific reference to -- to Augustine. However, I

11:34:19 10 believe he did have some -- some involvement with

11:34:22 11 the -- the production of this work.

11:34:23 12 Q. Have you reviewed the Augustine deposition?

11:34:27 13 A. I've seen some of it. Not the whole thing.

11:34:29 14 Q. Did Augustine's deposition testimony

11:34:31 15 corroborate the fact that he was involved in this

11:34:33 16 study, the McGovern study?

11:34:34 17 A. As I say, I don't -- I haven't seen the

11:34:37 18 whole -- whole of the deposition.

11:34:38 19 Q. So you have no basis to conclude that

11:34:40 20 actually Augustine was involved in the McGovern study.

11:34:45 21 A. Well as I -- as I say, I -- there was --

11:34:48 22 There is this issue of where some of the

11:34:49 23 funding was coming from for doing the McGovern study,

11:34:53 24 and I'm not putting my fingers on it right -- right at

11:34:56 25 the moment, so it was part of what I'm -- what I'm

11:34:59 1 saying.

11:34:59 2 Q. Where did you get the idea?

11:35:00 3 A. One of the -- one of the articles -- one of
11:35:03 4 the things that I've read -- that I read in preparing
11:35:05 5 this report.

11:35:06 6 Q. One of the things in the 19 sources listed
11:35:09 7 on Ex -- on page 14 of your report?

11:35:11 8 A. I believe it was somewhere in there, yes,
11:35:14 9 but --

11:35:17 10 I mean Albrecht, as I understand it, is --
11:35:21 11 was -- is an Augustine -- is working for Augustine.

11:35:25 12 Q. Does it say that on the paper?

11:35:27 13 A. It doesn't say that on the paper, but --

11:35:29 14 Q. You're assuming that to be true.

11:35:31 15 A. I think it says that in --

11:35:33 16 I think Albrecht says -- said that in his --
11:35:37 17 his deposition.

11:35:37 18 Q. Are you sure?

11:35:39 19 MR. GORDON: Object to the form of the
11:35:40 20 question.

11:35:42 21 A. I would have to review his testimony again,
11:35:47 22 but it -- it -- it has appeared many -- in -- in
11:35:52 23 many -- many things that they -- they are -- they
11:35:55 24 are -- they are together, and --

11:35:58 25 Q. 3M told you this.

11:36:01 1 A. Well I --

11:36:02 2 Q. You said that earlier, five minutes ago.

11:36:05 3 A. I --

11:36:06 4 They -- they -- they've -- they've said
11:36:07 5 that. I said -- as I say, I've also -- I've read it
11:36:11 6 in either a defi -- a deposition or one of the other
11:36:16 7 things that was -- that -- that I -- that I read, and
11:36:20 8 maybe in one of the other papers or something like
11:36:22 9 that.

11:36:22 10 Q. So you said you read Mr. Albrecht's
11:36:24 11 deposition; correct?

11:36:25 12 A. Yes.

11:36:25 13 Q. Okay. And are you familiar with the fact
11:36:28 14 that in Mr. Albrecht's deposition he said that the
11:36:32 15 data set that was analyzed in terms of conducting this
11:36:35 16 study contains three infections in the Hot Dog period?

11:36:38 17 MR. GORDON: Object to the form of the
11:36:40 18 question, misstates the testimony.

11:36:43 19 A. I -- I don't recall exactly what he said.

11:36:47 20 Q. So you have no recollection as to whether
11:36:49 21 Mr. Albrecht actually did say that the data set
11:36:54 22 contained three infections for the Hot Dog period.

11:36:58 23 A. I don't remember that.

11:36:59 24 Q. Well you rely on Mr. Albrecht's testimony in
11:37:03 25 determining that Albrecht Exhibit 10 in fact is the

11:37:07 1 final data set; correct?

11:37:11 2 MR. GORDON: Object to the form of the
11:37:12 3 question.

11:37:14 4 A. I -- I don't know that this is the data
11:37:19 5 set --

11:37:21 6 I mean the numbers don't agree with what was
11:37:24 7 tabulated in the -- in the -- in -- in the McGovern
11:37:27 8 paper, --

11:37:27 9 Q. Okay.

11:37:28 10 A. -- so I mean I'm not sure where Albrecht did
11:37:35 11 the tab -- how -- how Albrecht did -- did the
11:37:38 12 tabulation.

11:37:39 13 Q. But you rely on Mr. Albrecht's testimony
11:37:41 14 to -- in relying on using Exhibit 10; correct?

11:37:45 15 A. Using Exhibit 10. But then when you
11:37:49 16 tabulate Exhibit 10, you don't get what's in the
11:37:53 17 paper.

11:37:53 18 Q. Yeah. So you don't know whether Exhibit 10
11:37:55 19 is the final data set.

11:37:59 20 A. It --

11:38:03 21 I don't know that it is the data set that he
11:38:05 22 used with this paper or --

11:38:09 23 Maybe he made a mistake in the tabulation.
11:38:11 24 I don't know.

11:38:12 25 Q. Mr. -- or Dr. Borak doesn't conclude that it

11:38:16 1 was the final data set; does he?

11:38:20 2 A. I don't know.

11:38:21 3 MR. GORDON: Object to the form of the
11:38:22 4 question, lacks foundation.

11:38:23 5 Q. He called it the apparent data set; doesn't
11:38:27 6 he?

11:38:27 7 MR. GORDON: Same objection.

11:38:28 8 A. As I say, I have not -- I have not seen his
11:38:30 9 report.

11:38:30 10 Q. Okay.

11:38:39 11 (Exhibit 15 was marked for
11:38:40 12 identification.)

11:38:40 13 BY MR. SACCHET:

11:38:46 14 Q. Exhibit 15 is the October 7, 2016 deposition
11:38:50 15 of Mr. Albrecht; correct, Dr. Holford?

11:38:55 16 A. That's correct.

11:38:55 17 Q. Okay. If you could please turn to page 158
11:39:03 18 of the transcript, which is page 41 at the bottom. Do
11:39:09 19 you see that?

11:39:13 20 A. Yes.

11:39:18 21 Q. Mr. Gordon asked, "If you count the
11:39:21 22 infections for that time period, June 1st 2010, to
11:39:26 23 December 31st, 2010, there are actually four,
11:39:29 24 correct?"

11:39:31 25 Do you see that question?

11:39:32 1 A. Yes.

11:39:32 2 Q. And Mr. Albrecht responds, "I would have to
11:39:35 3 physically count these, but that's not what our data
11:39:38 4 set says here. The data set that was analyzed there
11:39:41 5 was three."

11:39:43 6 A. Yes.

11:39:44 7 Q. Are you aware that Mr. Albrecht testified
11:39:47 8 that the data set that was analyzed had three deep
11:39:51 9 joint infections instead of the four that Mr. Gordon
11:39:55 10 had asked about?

11:39:57 11 A. That's what -- that's what he's saying here,
11:39:59 12 and that corresponds to the --

11:40:02 13 Q. The study.

11:40:03 14 A. -- the -- the -- the -- the Table -- the
11:40:06 15 Table II in this -- in the paper.

11:40:08 16 Q. But in your report you say that the results
11:40:11 17 by McGovern are incorrect because they arise from an
11:40:15 18 incorrect tabulation error; an error is recognized in
11:40:19 19 the deposition by Albrecht.

11:40:22 20 A. You're looking at one piece of it here.
11:40:24 21 There's elsewhere that he -- that -- that he talks
11:40:29 22 about a -- that -- that there were -- there was
11:40:33 23 apparently an error that they recognized later.

11:40:38 24 Q. You think Mr. Albrecht said that?

11:40:40 25 A. I thought he did somewhere. I -- I don't

11:40:43 1 remember exactly where -- where it is.

11:40:45 2 Reed said it.

11:40:47 3 Q. This is Mr. Albrecht. Do you think Mr.

11:40:50 4 Albrecht said there was an error?

11:40:52 5 A. I seem to recall he -- that -- that there

11:40:54 6 was. I don't remember exactly where -- where it is.

11:40:58 7 It's a fairly long report.

11:41:00 8 Q. Let's keep going then. If you can go to

11:41:02 9 internal page 142, page 37 at the bottom, line 16, Mr.

11:41:17 10 Gordon asked, "I have something that's going to help.

11:41:20 11 But first I want to establish that -- that is a

11:41:23 12 printout of the data that Dr. Reed would have provided

11:41:26 13 to you and from which you generated your statistical

11:41:28 14 analysis that became the observational component of

11:41:32 15 Exhibit 8."

11:41:33 16 Do you see that question?

11:41:33 17 A. Yes.

11:41:33 18 Q. I'll represent to you that Exhibit 8 is the

11:41:35 19 McGovern study --

11:41:36 20 A. Okay.

11:41:37 21 Q. -- and I'll also represent to you that the

11:41:38 22 data set that Mr. Gordon is referring to is Albrecht

11:41:41 23 Exhibit 10.

11:41:41 24 A. Okay.

11:41:42 25 Q. The answer is, "I'm assuming, but there's no

11:41:45 1 way for me to verify something like this."

11:41:49 2 A. Okay.

11:41:49 3 Q. So Mr. Albrecht didn't know whether or not
11:41:52 4 Albrecht Exhibit 10 was the final data set, correct,
11:41:55 5 based on this testimony?

11:41:58 6 A. I -- I --

11:41:59 7 Yeah. Apparently, yeah.

11:42:01 8 Q. But you have concluded that, based on Mr.
11:42:02 9 Albrecht's testimony, that Albrecht Exhibit 10 is the
11:42:06 10 final data set; is that correct?

11:42:09 11 MR. GORDON: Object to the form of the
11:42:10 12 question, misstates his test -- misstates prior
11:42:13 13 testimony.

11:42:14 14 Q. Is your testimony not that Albrecht Exhibit
11:42:18 15 10 is the final data set?

11:42:19 16 MR. GORDON: Same objection.

11:42:20 17 A. I don't -- I don't --

11:42:22 18 I'm taking Exhibit 10 as it -- as it -- as
11:42:26 19 it is. I mean what --

11:42:31 20 What do you mean by "final data set?"

11:42:32 21 Q. Well you've already said that the data set
11:42:35 22 that is in Albrecht 10 is not the data that was in the
11:42:39 23 study; correct?

11:42:41 24 A. A tabulation based on -- based on that --
11:42:45 25 that data set doesn't agree with the paper.

11:42:50 1 Q. Yeah.

11:42:50 2 A. Yeah.

11:42:51 3 Q. And Mr. Albrecht in this testimony is saying
11:42:53 4 he doesn't know whether it's the final data set.

11:42:57 5 A. Okay.

11:42:58 6 Q. And Mr. Albrecht also said in the testimony
11:43:00 7 we read a moment ago that there were three infections
11:43:04 8 in the Hot Dog arm that were analyzed with respect to
11:43:05 9 the paper; correct?

11:43:06 10 A. That's --

11:43:07 11 He's, I assume, re -- reporting back what --
11:43:10 12 what was actually published in the paper, what this
11:43:14 13 tabulation that's in the paper showed.

11:43:16 14 Q. He says the data set that was analyzed there
11:43:20 15 was three.

11:43:22 16 A. So what is he referring --

11:43:24 17 When he says "data set," what does he mean?
11:43:26 18 I don't know quite what he -- what he's referring to.
11:43:29 19 Is he referring to the data -- the tabulation that was
11:43:32 20 made from the data, or is he talking about the -- the
11:43:35 21 original file?

11:43:38 22 Q. You're aware that not even Mr. Gordon knows
11:43:41 23 whether Exhibit 10 is the final data set; correct?

11:43:44 24 MR. GORDON: Object to the form of the
11:43:45 25 question, lack of foundation.

11:43:47 1 A. I don't know what Mr. Gordon knows or
11:43:51 2 doesn't know about that.

11:43:51 3 Q. Let's look at page 163, which is 42 at the
11:43:56 4 bottom. Are you there, doctor?

11:44:05 5 A. Okay.

11:44:06 6 Q. Line 17, Mr. Gordon asks -- or states, "And
11:44:11 7 I want to make it very clear, I have no idea if
11:44:14 8 Exhibit 10 is the original data" --

11:44:17 9 Albrecht answers: "I don't either."

11:44:20 10 Do you see that?

11:44:21 11 A. Okay.

11:44:22 12 Q. So Mr. Gordon doesn't know if it's the final
11:44:24 13 data set, Mr. Albrecht doesn't know whether it's the
11:44:26 14 final data set, Mr. Borak in his report uses the word
11:44:30 15 "apparent" data set, you don't know whether it's the
11:44:33 16 final data set --

11:44:34 17 A. Well the question is not "final," question
11:44:38 18 is "original."

11:44:38 19 Q. Okay. So let's say the original data set.

11:44:40 20 A. Okay.

11:44:41 21 Q. Mr. Gordon doesn't know if Exhibit 10 is the
11:44:44 22 original data set.

11:44:45 23 A. Okay.

11:44:46 24 Q. Mr. Albrecht also doesn't know whether
11:44:48 25 Exhibit 10 is the original data set.

11:44:50 1 A. Yeah.

11:44:51 2 Q. Mr. Borak also doesn't know whether Exhibit
11:44:53 3 10 is the original data set.

11:44:55 4 A. Okay.

11:44:55 5 Q. And you don't know.

11:44:56 6 A. I don't.

11:45:04 7 Q. To the extent that you rely on Albrecht
11:45:06 8 Exhibit 10, not knowing whether or not it's the
11:45:08 9 original data set, it could be a data artifact issue;
11:45:12 10 could it not?

11:45:14 11 MR. GORDON: Object to the form of the
11:45:15 12 question.

11:45:18 13 A. If -- if there's an error in -- in --

11:45:21 14 I mean if -- if the file is not the correct
11:45:23 15 data, then there -- there could be -- there -- there
11:45:28 16 would be a problem with -- with the analysis.

11:45:30 17 Q. And -- and you don't know whether or not
11:45:33 18 there is a problem with the data.

11:45:34 19 A. I don't know. I don't know if there is or
11:45:36 20 if there is not.

11:45:37 21 Q. You know that there's a missing page.

11:45:40 22 A. You --

11:45:40 23 There is one missing page.

11:45:42 24 Q. You know that the missing page contains or
11:45:45 25 may not contain information regarding deep joint

11:45:48 1 infection during the Bair Hugger study period;

11:45:53 2 correct?

11:45:53 3 A. It was --

11:45:54 4 I wasn't looking at the individual pages, as

11:45:57 5 I've -- as I've said, --

11:45:58 6 Q. Yeah.

11:45:59 7 A. -- and -- and my under -- I --

11:46:05 8 I don't know if this is the same data set

11:46:08 9 that -- that Albrecht was -- was looking at when he

11:46:13 10 did the -- his -- his calculations.

11:46:17 11 Q. Thank you.

11:46:18 12 Do you have any other reason to assume that

11:46:25 13 Albrecht Exhibit 10 is the original or final data set?

11:46:31 14 MR. GORDON: Object to the form of the

11:46:32 15 question.

11:46:35 16 A. I mean why is Exhibit 10 as part of the

11:46:41 17 Albrecht testimony?

11:46:47 18 Q. Why is it?

11:46:47 19 A. Yeah. How did it get there?

11:46:49 20 Q. Mr. Gordon marked --

11:46:51 21 A. Okay.

11:46:52 22 Q. -- Exhibit 10 at the deposition.

11:46:53 23 A. And I mean the assumption is is that that is

11:47:00 24 the data on which this is based.

11:47:03 25 Q. You're making that assumption even though

11:47:05 1 Mr. Albrecht has said that the data set that was
11:47:07 2 analyzed, there was three deep joint infections.

11:47:11 3 A. Yes.

11:47:12 4 Q. You're making that assumption even though
11:47:14 5 Mr. Gordon said that Exhibit 10, he didn't know
11:47:17 6 whether it was the original data set.

11:47:20 7 MR. GORDON: You're -- you're actually --
11:47:22 8 You're reading only a portion of the
11:47:23 9 testimony and you're --

11:47:26 10 MR. SACCHET: I think you're testifying
11:47:26 11 right now, Mr. Gordon.

11:47:27 12 MR. GORDON: Well no. I mean --
11:47:29 13 But come on.

11:47:30 14 MR. SACCHET: I'm --

11:47:30 15 MR. GORDON: If you're going to quote me,
11:47:33 16 quote what I said; don't make -- don't -- don't --

11:47:37 17 MR. SACCHET: Okay.

11:47:37 18 MR. GORDON: -- don't screw up the record by
11:47:38 19 selectively quoting half of what I said.

11:47:39 20 MR. SACCHET: Yeah. I'll read the sentence.

11:47:41 21 MR. GORDON: Read the whole sentence.

11:47:42 22 MR. SACCHET: "And I want -- I want to make
11:47:43 23 it very clear, I have no idea if Exhibit 10 is the
11:47:46 24 original data" --

11:47:47 25 MR. GORDON: And you see the thing it says

11:47:49 1 after that? It says dash --

11:47:50 2 MR. SACCHET: Dash.

11:47:51 3 MR. GORDON: -- and continues on with the
11:47:52 4 rest of what I said.

11:47:54 5 MR. SACCHET: -- "or the -- the newer data
11:47:56 6 that's slightly conflicted."

11:47:58 7 Q. Does that change your mind?

11:48:01 8 A. What is the question?

11:48:04 9 Q. The question is: Mr. Albrecht has said that
11:48:06 10 there was three infections in the Hot Dog period based
11:48:09 11 on the data that was analyzed.

11:48:10 12 A. Yes.

11:48:11 13 Q. Mr. Gordon has said he doesn't know if
11:48:15 14 Exhibit 10 is the original data or the newer data
11:48:17 15 that's slightly conflicted.

11:48:19 16 A. Yes.

11:48:20 17 Q. Dr. Borak has said that it apparently could
11:48:24 18 be.

11:48:26 19 A. Yes.

11:48:28 20 Q. You just told me that you're assuming
11:48:29 21 Albrecht Exhibit 10 is the final data set.

11:48:32 22 MR. GORDON: I object to the form of the
11:48:34 23 question.

11:48:34 24 A. Well I'm -- I'm -- that --

11:48:35 25 Exhibit 10 is the data on which I did the

11:48:37 1 analysis, --

11:48:37 2 Q. Okay.

11:48:38 3 A. -- so in --

11:48:44 4 The total number of infections in my table

11:48:51 5 exactly -- are exactly the same as what are in

11:48:54 6 McGovern's paper.

11:48:57 7 Q. Okay. Do you rely on anything else to

11:49:01 8 conclude that Albrecht Exhibit 10 is the original

11:49:06 9 data?

11:49:06 10 MR. GORDON: Objection --

11:49:07 11 Q. That's -- that's -- that's the scope of the

11:49:08 12 question.

11:49:08 13 MR. GORDON: Objection, asked and answered.

11:49:09 14 Q. Do you rely on anything else?

11:49:11 15 MR. GORDON: Objection, asked and answered.

11:49:13 16 He's also testified the other things he relied on.

11:49:18 17 MR. SACCHET: I don't recall the other

11:49:19 18 testimony. I'm not -- I'm not --

11:49:20 19 MR. GORDON: All right. Fair enough.

11:49:21 20 A. I mean I -- I've -- I'm assuming that those

11:49:24 21 are --

11:49:24 22 The data that -- that formed the basis of --

11:49:28 23 of that -- of the McGovern paper, that they're in --

11:49:32 24 that they're in that file.

11:49:33 25 Q. I'm going to ask the question again. Do you

11:49:36 1 rely on anything else in making that assumption?

11:49:42 2 A. Well I've --

11:49:43 3 There are other parts of the data that have
11:49:47 4 been given as some of the other -- other evidence.

11:49:50 5 Q. What?

11:49:51 6 A. Well there's a list of -- of the infections
11:49:57 7 that I think McGovern --

11:50:01 8 Q. Okay.

11:50:02 9 A. -- provided, the evi -- well I think
11:50:08 10 it's -- I think it was Exhibit 16 in his -- his
11:50:12 11 deposition.

11:50:12 12 Q. Okay.

11:50:13 13 A. And, you know, it's -- it's a different
11:50:15 14 file. There are differences in there, differences in
11:50:18 15 the way the dates are recorded because we're dealing
11:50:21 16 with the way the Brits give dates and the way we give
11:50:26 17 dates in the U.S. and things like that. But you can
11:50:33 18 match up the -- those two -- two files and they -- you
11:50:39 19 know, they -- they agree. And so it -- that has given
11:50:46 20 me more confidence that the data that we're looking --
11:50:50 21 that I'm looking at really corresponds to the same
11:50:51 22 data --

11:50:51 23 Q. Okay.

11:50:52 24 A. -- that -- that forms the basis of the --
11:50:55 25 the report in McGovern.

11:50:56 1 Q. So anything else in addition to McGovern 16?

11:50:59 2 MR. GORDON: Again, asked and answered.

11:51:04 3 A. Yeah. Anything --

11:51:09 4 It's 10, 16 and -- well, an analysis of

11:51:15 5 those. I'm not recalling other sources at the moment,

11:51:18 6 but --

11:51:20 7 Q. Okay. Thank you. That answers the

11:51:23 8 question.

11:51:23 9 A. Yeah.

11:51:23 10 Q. Before we get to McGovern 16, I'd like to

11:51:26 11 show you a few additional documents.

11:51:37 12 (Exhibit 16 was marked for

11:51:39 13 identification.)

11:51:39 14 BY MR. SACCHET:

11:51:41 15 Q. Have you seen this document before,

11:51:43 16 Professor Holford?

11:51:46 17 A. I don't recall seeing this.

11:51:47 18 Q. Okay. It has been produced by Mr. Albrecht

11:51:51 19 based on the Bates number in the bottom right-hand

11:51:54 20 corner; correct? It --

11:52:03 21 The bottom right-hand Bates number has the

11:52:05 22 prefix "Albrecht."

11:52:06 23 A. Oh, I'm sorry. Yes. Yes.

11:52:09 24 Q. And the top of the page is entitled

11:52:11 25 "LogisticRegression, Mark Albrecht, March 11, 2016."

11:52:15 1 A. Correct.

11:52:16 2 Q. That's a number of years after the
11:52:18 3 publication of the McGovern study; correct?

11:52:20 4 A. Okay. Yeah. Yes, it is.

11:52:23 5 Q. And the first paragraph says, "Below is the
11:52:26 6 analysis source code and data supporting the
11:52:28 7 publication Forced-air warming linked to
11:52:30 8 periprosthetic total joint replacement infections.

9 This s an R-markdown document, so it can be run
11:52:38 10 directly in the R-Console to produce -- to reproduce
11:52:38 11 the results." Do you see that?

11:52:40 12 A. Yes.

11:52:41 13 Q. And then the next title is "Raw Data" and it
11:52:45 14 says, "The raw infection data by hospital is, colon;"
11:52:47 15 correct? That's -- that's what it says, "The raw
11:52:50 16 infection data by hospital is, colon."

11:52:53 17 A. Yes.

11:52:53 18 Q. And there's some quotes.

11:52:54 19 If you look on the fourth line of that we
11:52:58 20 see "c(10, 11, 10, 21, 3, 32);" correct?

11:53:04 21 A. Yes.

11:53:04 22 Q. And then we see "NonInfections equal c(1087,
11:53:09 23 378, 1087, 656, 368, 1034)." Do you see that?

11:53:14 24 A. Yes.

11:53:15 25 Q. Do the numbers 3, 32, 368 and 1034 ring a

11:53:20 1 bell?

11:53:20 2 MR. GORDON: Object to the form of the
11:53:21 3 question.

11:53:24 4 A. No.

11:53:27 5 Q. The numbers 3 and 32 are not the same
11:53:30 6 numbers that were used in the McGovern publication
11:53:33 7 with respect to the total number of infections in the
11:53:36 8 Hot Dog arm versus the Bair Hugger arm?

11:53:42 9 A. Which --

11:53:47 10 I don't understand what you're asking.

11:53:48 11 Q. Okay. In the Bair Hugger period, how many
11:53:51 12 infections did the authors report with respect to the
11:53:54 13 Hot Dog, the authors report in Table II?

11:53:57 14 A. Table II.

11:54:12 15 Q. Did they report three in Table II, Hot Dog
11:54:15 16 infections?

11:54:16 17 A. Yeah.

11:54:16 18 Q. Okay. How many Bair Hugger infections did
11:54:18 19 they report in the McGovern study?

11:54:21 20 A. Thirty-two.

11:54:22 21 Q. Is that the same number that we see here?

11:54:30 22 A. Oh, oh, I see. This is --

11:54:32 23 I'm -- I'm sorry, I don't -- I'm not really
11:54:34 24 understanding this code.

11:54:36 25 Okay. So what is this c?

11:54:43 1 Q. "Center" perhaps.

11:54:45 2 A. No. I think it's a vector usually in R,
11:54:49 3 it's a vector and it --

11:54:54 4 Q. My -- my -- my question --

11:54:56 5 MR. GORDON: Counsel, I mean, you know --

11:54:58 6 A. I don't know what --

11:54:59 7 MR. SACCHET: Corey, again it's a speaking
11:55:00 8 objection. If you want to object, go for it.

11:55:03 9 MR. GORDON: Yeah. If you're representing
11:55:04 10 this has anything to do with the McGovern paper --

11:55:06 11 MR. SACCHET: Yeah?

11:55:07 12 MR. GORDON: -- as opposed to what the
11:55:08 13 testimony was, which was this was what turned into the
11:55:10 14 Augustine -- recently published Augustine paper, you
11:55:14 15 know, you've got -- you've got an obligation to --
11:55:18 16 to -- to be truthful.

11:55:19 17 MR. SACCHET: I'm look -- I --

11:55:20 18 My questions are solely about the numbers.

11:55:22 19 Q. Professor Holford, were there three
11:55:23 20 infections in the Hot Dog period in the McGovern
11:55:26 21 study --

11:55:26 22 A. Looking at the paper, yes.

11:55:28 23 Q. -- as reported in Table II?

11:55:30 24 A. As reported in Table II, yes.

11:55:32 25 Q. Were there 32 infections as reported in

11:55:34 1 Table II from the Bair Hugger period?

11:55:38 2 A. That's correct.

11:55:38 3 Q. Were there 368 non-infections in the Hot Dog
11:55:39 4 period reported in the McGovern study?

11:55:41 5 A. Yes.

11:55:41 6 Q. Were there a hundred and -- 1,034 non-
11:55:43 7 infections reported in the Bair Hugger -- in the
11:55:46 8 McGovern study with respect to the Bair Hugger arm?

11:55:49 9 A. Yes.

11:55:49 10 Q. These numbers are the same as what was
11:55:51 11 reported in the Bair Hugger study, the numbers are the
11:55:53 12 same -- it's a simple question -- as reported in the
11:55:55 13 McGovern study.

11:55:56 14 A. The last -- the last two -- two columns of
11:56:02 15 this vector do correspond to that. I don't know what
11:56:06 16 the other numbers that are there correspond to. I
11:56:10 17 don't know what the 10 --

11:56:12 18 The 1087, for example, what is that?

11:56:14 19 Q. I'm not asking about those numbers.

11:56:16 20 A. Well I have to understand when I'm reading
11:56:21 21 someone's code. I don't understand what it's
11:56:22 22 referring to.

11:56:23 23 Q. And the date is March 11, 2016; correct?

11:56:25 24 A. Yes.

11:56:27 25 Q. Okay.

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11:56:44 1 MR. GORDON: I'm going to need a quick break
11:56:46 2 in the near future, --
11:56:47 3 MR. SACCHET: Okay.
11:56:48 4 MR. GORDON: -- whenever it's convenient.
11:56:51 5 MR. SACCHET: Okay. Take about five minutes
11:56:52 6 if you don't mind.
11:56:53 7 MR. GORDON: Right now?
11:56:54 8 MR. SACCHET: Just in five minutes.
11:56:55 9 MR. GORDON: Oh, that's fine.
11:57:06 10 (Exhibit 17 was marked for
11:57:07 11 identification.)
11:57:07 12 BY MR. SACCHET:
11:57:15 13 Q. This is a document with a subject line "Full
11:57:19 14 workup of the stats you requested;" correct?
11:57:23 15 A. Yes.
11:57:23 16 Q. It's been previously marked as McGovern 23;
11:57:26 17 correct?
11:57:26 18 A. I don't know where you're getting that from.
11:57:34 19 Q. The bottom right of the page, there's a
11:57:36 20 stamp there and it says Exhibit --
11:57:37 21 A. Oh, I see.
11:57:38 22 Q. -- Exhibit McGovern 23.
11:57:41 23 A. Yeah.
11:57:43 24 Q. Have you seen this document before?
11:57:44 25 A. No.

11:57:45 1 Q. This was a document that was --

11:57:49 2 I'll represent to you this is a document
11:57:51 3 that was marked at the McGovern deposition.

11:57:55 4 You reviewed other exhibits from the
11:57:57 5 McGovern deposition; correct?

11:58:01 6 A. I looked at, I think, some of them, yeah.

11:58:03 7 Q. One of them was McGovern Exhibit 16;
11:58:07 8 correct?

11:58:07 9 A. Oh. Yes, I did.

11:58:07 10 Q. But you didn't see this one.

11:58:09 11 A. No, I didn't look at this one.

11:58:10 12 Q. Did you get all of the exhibits from these
11:58:12 13 depositions or just a select handful?

11:58:15 14 A. I think they were all there. I didn't -- I
11:58:18 15 didn't do an audit to check, but --

11:58:20 16 Q. How did you determine which ones to look at
11:58:22 17 and which ones not to look at?

11:58:25 18 A. It was what was most relevant to the
11:58:30 19 analysis that I was doing.

11:58:32 20 Q. How did you make that determination?

11:58:34 21 A. Well I was -- figured out what I was
11:58:40 22 interested in for that particular part of the report I
11:58:42 23 was working on.

11:58:43 24 Q. Okay. Let's see if this piques your
11:58:46 25 interest. The first e-mail is dated November 29th,

11:58:49 1 2011; correct?

11:58:50 2 A. Yes.

11:58:51 3 Q. And that is after publication of the

11:58:52 4 McGovern study; correct?

11:58:54 5 A. I believe so, yes.

11:58:55 6 Q. Okay. And in the e-mail on November 30th,

11:59:03 7 2011 from Mike Reed to Mark Albrecht, the text states,

11:59:07 8 "Mark

11:59:07 9 "This is great. I am very grateful.

11:59:09 10 So - for clarity - this chart is the same as

11:59:12 11 the one in our paper but with longer follow up?"

11:59:15 12 Do you see that?

11:59:15 13 A. Okay. Yes.

11:59:17 14 Q. And then the last line says, "You are 3.6

11:59:20 15 times more likely to get an infection on FAW than

11:59:25 16 CFW?" Correct?

11:59:28 17 Last line of that same paragraph.

11:59:30 18 A. Yes.

11:59:30 19 Q. Okay. Now if we turn the page, Table 1 does

11:59:36 20 in fact look like Table II in the McGovern study;

11:59:41 21 correct?

11:59:41 22 A. It looks like it, yes.

11:59:43 23 Q. Okay. Let's look at the number of patients

11:59:48 24 developing infection in the conductive fabric warming

11:59:51 25 group. Do you see the number seven?

11:59:52 1 A. Yes.

11:59:53 2 Q. And the percentage .9?

11:59:58 3 A. Yes.

11:59:58 4 Q. And then there were 792 of whom did not

12:00:02 5 develop an infection; correct?

12:00:03 6 A. Yes.

12:00:04 7 Q. That's approximately double the amount of

12:00:06 8 patients that were originally analyzed in the Bair

12:00:09 9 Hugger period; correct?

12:00:09 10 A. Yes.

12:00:10 11 Q. Okay. So this appears to be an extended

12:00:12 12 data set; correct?

12:00:13 13 A. It appears that they've extended the

12:00:17 14 conductive fabric, --

12:00:18 15 Q. Okay.

12:00:19 16 A. -- yeah.

12:00:20 17 Q. Let's look at the forced-air group. How

12:00:24 18 many individuals developed an infection?

12:00:27 19 A. Thirty-three.

12:00:29 20 Q. That's two more than the 31 that you use in

12:00:32 21 your report; correct?

12:00:33 22 A. Okay.

12:00:35 23 Q. Is that correct?

12:00:36 24 A. Appears to be correct. Yeah, I used --

12:00:41 25 Q. Thirty-one; correct?

12:00:44 1 A. I have 32.

12:00:45 2 Well wait, I'm sorry. Yeah, 31, that's

12:00:57 3 right.

12:00:57 4 Q. This is two more.

12:00:58 5 A. It is two more.

12:01:00 6 Q. And the percent of infection is 3.1 in the

12:01:05 7 forced-air group; correct?

12:01:06 8 A. Yes.

12:01:07 9 Q. That is in fact higher than the percent that

12:01:10 10 was reported in the study; correct?

12:01:11 11 A. Yes.

12:01:12 12 Q. That's higher than the percent that you use

12:01:14 13 in your report; correct?

12:01:15 14 A. Yes.

12:01:16 15 Q. Do you have any basis to conclude that this

12:01:22 16 data is not the final data set?

12:01:24 17 MR. GORDON: Which data?

12:01:25 18 MR. SACCHET: The numbers reported here.

12:01:27 19 MR. GORDON: In --

12:01:28 20 A. What do you mean by "final data set?" I

12:01:30 21 mean --

12:01:31 22 MR. GORDON: -- Exhibit 17.

12:01:31 23 A. This is very different from --

12:01:33 24 It's not the data set that appears in

12:01:34 25 McGovern.

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12:01:35 1 Q. With respect to the forced-air group, there
12:01:37 2 are two more infections; correct?

12:01:40 3 A. There -- there are.

12:01:41 4 MR. GORDON: Two more infections than he
12:01:43 5 did -- he reported.

12:01:45 6 A. Two more than I -- than I reported. It is
12:01:48 7 one more than McGovern reported.

12:01:50 8 Q. Okay.

12:01:51 9 A. And the total number is --

12:01:54 10 What is it?

12:01:57 11 Q. One thousand --

12:01:58 12 A. 1,098.

12:02:01 13 Q. You mean 68?

12:02:06 14 A. Thirty-two and 1066.

12:02:10 15 Oh, I'm sorry, 1068 is the total.

12:02:12 16 Q. Yeah.

12:02:13 17 A. So this is --

12:02:16 18 This says 1065 are in this report you're
12:02:21 19 just showing me.

12:02:22 20 Q. Uh-huh. Does this calculation give you any
12:02:26 21 pause that perhaps there was more Bair Hugger
12:02:29 22 infections than the amount that you've reported in
12:02:32 23 your report?

12:02:34 24 MR. GORDON: Object to the form of the
12:02:35 25 question.

12:02:37 1 A. Yeah. I -- I -- I don't know the sources --

12:02:41 2 the sources of these data. I mean it's --

12:02:45 3 There's also less -- fewer subjects.

12:02:47 4 Q. The source of the data is from Mr. Albrecht;

12:02:51 5 is it not?

12:02:51 6 MR. GORDON: Object to the form of the

12:02:52 7 question, lack of foundation.

12:02:58 8 A. Well it's -- it's based -- I gather -- well

12:03:06 9 I don't know where -- where --

12:03:08 10 Where is this data? Is this part of the

12:03:10 11 e -- no, this is not part of the e-mail. Where does

12:03:13 12 Table 1 come from in this exhibit?

12:03:15 13 Q. On the prior page Mr. Reed says, "So - for

12:03:18 14 clarity - this chart is the same as the one in our

12:03:21 15 paper but with longer follow up?" Correct?

12:03:25 16 A. "This chart," so what is this?

12:03:27 17 Q. We read that earlier.

12:03:28 18 A. Is this the percent of --

12:03:30 19 Results.pdf, what is it? What are we

12:03:35 20 looking at?

12:03:35 21 Q. We're looking at the table Mr. Reed is

12:03:37 22 referring to in his e-mail.

12:03:40 23 A. So this is an attachment to the e-mail, --

12:03:41 24 Q. Yes.

12:03:42 25 A. -- is that what you're saying?

12:03:43 1 Q. Yes.

12:03:43 2 A. Okay. So -- okay. So you're asking me
12:04:01 3 about the number that developed, so they're reporting
12:04:05 4 33 in this. In their -- in their paper that they
12:04:11 5 published they said there were 32.

12:04:14 6 Q. So it actually went up from what was
12:04:16 7 published in their report.

12:04:18 8 A. Went up from what was published, went up
12:04:21 9 one.

12:04:21 10 Q. Yeah.

12:04:21 11 A. It's not the file they're looking at. The
12:04:24 12 total number of cases is -- in this Table 1 goes
12:04:27 13 down --

12:04:28 14 Q. Uh-huh.

12:04:28 15 A. -- to 1065 while here it was 10 -- 1066.

12:04:38 16 Q. So why did you decide to go down instead of
12:04:41 17 up?

12:04:42 18 A. Why did I decide to go down --

12:04:44 19 Q. You report 31 infections, this document
12:04:47 20 reports 33 for forced-air warming. Why did you go
12:04:50 21 down?

12:04:50 22 A. Oh, because -- because I tabulated the --
12:04:52 23 the file that I -- that I showed you, --

12:04:55 24 Q. Okay.

12:04:56 25 A. -- ran that through the statistical

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12:04:58 1 software, and that was the tabulation that -- that I

12:05:01 2 got using SAS.

12:05:07 3 Q. And this document shows otherwise.

12:05:10 4 A. This document is not showing those same

12:05:13 5 results, --

12:05:13 6 Q. Okay.

12:05:14 7 A. -- yes.

12:05:15 8 MR. SACCHET: Let's take a break.

12:05:16 9 THE REPORTER: Off the record, please.

12:05:18 10 (Recess taken.)

12:12:27 11 (Exhibit 18 was marked for

12:12:29 12 identification.)

12:12:29 13 BY MR. SACCHET:

12:12:30 14 Q. Dr. Holford, Exhibit 18, which was

12:12:34 15 previously marked as McGovern 16, is the document that

12:12:40 16 you also reviewed in opining on the number of

12:12:44 17 infections in the Bair Hugger study; correct?

12:12:47 18 A. Yes.

12:12:49 19 Q. The document is not dated; is it?

12:12:56 20 A. It doesn't appear to be.

12:12:58 21 Q. So you do not know when this document was

12:13:06 22 finalized; correct?

12:13:07 23 A. No.

12:13:09 24 Q. Are you aware that Mr. McGovern never

12:13:20 25 testified that this was the final data set?

12:13:26 1 A. I don't know what he said on it.

12:13:28 2 Q. You don't know one way or another whether
12:13:31 3 Mr. McGovern said this was the final data set or was
12:13:34 4 not the final data set.

12:13:35 5 A. No, I don't.

12:13:36 6 Q. You reviewed Mr. McGovern's deposition;
12:13:39 7 correct?

12:13:39 8 A. I did. I just don't recall his comment
12:13:41 9 on -- on -- on this particular data set.

12:13:43 10 Q. In the event that Mr. McGovern made no
12:13:46 11 comment regarding whether or not this was the final
12:13:48 12 data set, would that impact your opinion as to whether
12:13:51 13 it is or is not?

12:13:58 14 A. I mean I don't -- I don't know where --

12:14:01 15 I mean I'm taking -- taking the data set at
12:14:04 16 face value, and he is talking about it and I --
12:14:08 17 it's -- so I'm assuming it -- it --

12:14:13 18 Well it formed the basis of what my -- what
12:14:16 19 my opinions are. That's -- this is what I -- I based
12:14:20 20 it on.

12:14:20 21 Q. Well in your report you say that "The
12:14:22 22 results in McGovern are incorrect because they arise
12:14:24 23 from an incorrect tabulation. An error is recognized
12:14:27 24 in the depositions by Albrecht, Reed and McGovern."

12:14:31 25 A. That there is a --

12:14:33 1 Well that's referring to not this -- not --

12:14:36 2 not this exhibit, that's referring to the paper.

12:14:41 3 Q. So in your --

12:14:42 4 A. And so I mean an initial source of -- of --

12:14:48 5 of the -- of the -- of the problem I think is -- was

12:14:54 6 in Reed's testimony.

12:14:54 7 Q. Okay.

12:14:55 8 A. Reed testified that there was one more

12:14:57 9 infection in each group.

12:14:58 10 Q. We'll get there. But with respect --

12:15:00 11 A. Okay.

12:15:01 12 Q. -- to Mr. -- Dr. McGovern, --

12:15:03 13 A. Okay.

12:15:03 14 Q. -- Dr. McGovern never says anything about a

12:15:06 15 tabulation error; correct?

12:15:10 16 MR. GORDON: Object to the form of the

12:15:11 17 question, assumes facts not in evidence.

12:15:14 18 A. I don't -- I don't recall exactly what

12:15:16 19 doc -- what -- all of the details of -- of McGovern.

12:15:21 20 Q. So you don't know whether or not he said

12:15:23 21 there was a tabulation error; correct?

12:15:25 22 A. I -- I don't remember.

12:15:28 23 Q. Okay. Your report says that he did

12:15:31 24 recognize an error; correct?

12:15:34 25 A. I may have said that.

12:15:44 1 Q. Pages two and three. I don't want to spend

12:15:46 2 a ton of time on this, but --

12:15:52 3 A. I mean there's --

12:15:56 4 Q. -- the quote is --

12:15:57 5 A. I -- I -- I --

12:16:02 6 Q. Can I read you the quote?

12:16:05 7 A. Yes.

12:16:06 8 Q. "The results by McGovern are incorrect,

12:16:09 9 however, because they arise from an incorrect

12:16:11 10 tabulation. An error is recognized in the depositions

12:16:14 11 by Albrecht, Reed and McGovern."

12:16:18 12 A. Okay. The tabulation, based on this, if you

12:16:22 13 look at -- count the numbers in here, I think they

12:16:25 14 agree with -- with my tabulation --

12:16:28 15 Q. Okay.

12:16:29 16 A. -- in -- in terms of the numbers and the

12:16:32 17 dates in which these -- these occur, and so that's

12:16:36 18 based on this -- this table --

12:16:39 19 Q. So you --

12:16:39 20 A. -- of data.

12:16:40 21 Q. You're relying on the table, not Mr.

12:16:43 22 McGovern's testimony -- Dr. McGovern's testimony.

12:16:46 23 MR. GORDON: Object to the form of the

12:16:47 24 question.

12:16:48 25 A. I -- I -- I -- as I say, I don't recall

12:16:53 1 exactly where -- what McGovern said, if he says it or
12:16:57 2 not, but I -- but this is a big part of where -- that
12:17:03 3 forms the basis for that statement.

12:17:04 4 Q. But you don't know whether or not, sitting
12:17:06 5 here today, Mr. McGovern -- Dr. McGovern said that
12:17:11 6 there was a tabulation error or there was not a
12:17:13 7 tabulation error.

12:17:14 8 A. I don't recall --

12:17:15 9 Q. Okay.

12:17:15 10 A. -- this morning.

12:17:26 11 Q. If we could go back to the previous marked
12:17:29 12 document which is McGovern Exhibit 16 --

12:17:42 13 A. To which document?

12:17:43 14 Q. Exhibit 18 I believe.

12:17:44 15 A. Okay.

12:17:45 16 MR. GORDON: Eighteen? What -- what -- just
12:17:48 17 what is it?

12:17:50 18 THE WITNESS: McGovern 16 --

19 MR. SACCHET: McGovern 16 --

12:17:53 20 THE WITNESS: -- which is 18.

21 MR. SACCHET: -- which is 18.

12:17:54 22 THE WITNESS: Yeah, okay.

12:17:54 23 MR. GORDON: Oh.

12:17:56 24 Q. Did you review any other data sets that were
12:18:00 25 produced by Dr. McGovern?

12:18:08 1 A. I don't recall --

12:18:11 2 That were produced by him, no.

12:18:12 3 Q. If he had produced other data sets, how do
12:18:14 4 you know that this is the data set that includes the
12:18:20 5 data that was published in the McGovern study?

12:18:22 6 MR. GORDON: Object to the form of the
12:18:23 7 question, assumes facts not in evidence.

12:18:26 8 A. I -- I mean the whole -- the whole past of
12:18:32 9 where these files came from is -- is not something
12:18:35 10 that I saw.

12:18:36 11 Q. You don't know where they came from.

12:18:38 12 A. Well I -- I know who gave them to me.

12:18:40 13 Q. Who gave them to you?

12:18:41 14 A. 3M.

12:18:42 15 Q. But you don't know who produced these.

12:18:44 16 A. No.

12:18:45 17 Q. Okay. If we turn to the very last page of
12:18:52 18 this document, Exhibit 18, --

12:18:57 19 A. Okay.

12:18:59 20 Q. -- there is a condensed table, correct, with
12:19:02 21 various fields summing through --

12:19:06 22 Very last. The last page with a table on
12:19:15 23 it. I think you're looking at the first --

12:19:23 24 A. In my page it's Table 1.

12:19:25 25 Q. The front of the document has this stamp on

12:19:27 1 it, doctor, so that's the first page.

12:19:29 2 A. Oh, I see.

12:19:29 3 Q. Yeah. First --

12:19:30 4 It was marked, actually, on the reverse

12:19:33 5 side --

12:19:33 6 A. Okay.

12:19:33 7 Q. -- so that's where the confusion is.

12:19:35 8 If you turn to the last page, which is

12:19:39 9 actually, from what I can see on your document, the

12:19:40 10 one with the blue sticker on it --

12:19:41 11 A. That's the one I was looking at.

12:19:43 12 Q. Yeah.

12:19:43 13 A. Okay. Sorry.

12:19:44 14 Q. -- there are a number of fields here. I

12:19:47 15 recognize it's small and I apologize for that.

12:19:49 16 However, you reviewed this table; correct?

12:19:52 17 A. Yes.

12:19:53 18 Q. And column BJ is the date-of-surgery column;

12:20:04 19 correct?

12:20:04 20 A. Yes.

12:20:10 21 Q. Okay.

12:20:11 22 A. Appears to be, yeah.

12:20:12 23 Q. And in your report you single out row 44,

12:20:20 24 which has a date of surgery of 9/15/2007 --

12:20:24 25 A. Yes.

12:20:25 1 Q. -- and as coded as FAW; correct?

12:20:27 2 MR. GORDON: 2010.

12:20:28 3 MR. SACCHET: Oh, I'm sorry. Thank you, Mr.

12:20:30 4 Gordon.

12:20:31 5 Q. -- 9/15/2010 and as coded as forced-air

12:20:35 6 warming; correct?

12:20:36 7 A. That's correct.

12:20:37 8 Q. Okay. How do you know that it was

12:20:38 9 incorrectly coded as to the type of device instead of

12:20:43 10 the type of -- date?

12:20:46 11 A. I don't know that.

12:20:51 12 Q. But you're relying on the fact that this

12:20:53 13 surgery in fact occurred on September 15th, 2010;

12:20:58 14 correct?

12:20:58 15 A. That's right.

12:21:03 16 I mean if -- if the date is wrong and that

12:21:07 17 date should be, you know, sometime during the Bair

12:21:10 18 Hugger period, then not only the numerator would be

12:21:13 19 wrong but the denominator would be wrong as well. I

12:21:17 20 think the total number of cases is -- in my tabulation

12:21:24 21 is the same as, I believe --

12:21:32 22 Let me double check that. So 4037 --

12:21:58 23 No. I'm sorry. Yeah, I'm -- I'm assuming

12:22:01 24 that -- that that is -- that -- that the date is

12:22:06 25 correctly -- it was based --

12:22:08 1 My tabulation was based on the date that was
12:22:11 2 given.
12:22:11 3 Q. It was not based on the device coding.
12:22:13 4 A. Not the --
12:22:13 5 No.
12:22:16 6 Q. And if you could --
12:22:19 7 We're going to toggle back between two
12:22:21 8 different documents, so --
12:22:22 9 A. Okay.
12:22:23 10 Q. I don't want you to get too mixed up here,
12:22:26 11 but if you can go back to the McGovern study which we
12:22:29 12 had marked as Exhibit 13 in this deposition --
12:22:33 13 A. Okay.
12:22:34 14 Q. -- and pull that out.
12:22:41 15 A. Okay.
12:22:41 16 Q. And I just want you to hold Fig. 7, which is
12:22:45 17 in the back end of the McGovern study, next to the
12:22:51 18 table in front of you. So you can just pull up Fig.
12:22:54 19 7 in the McGovern study.
12:22:59 20 MR. GORDON: And what is --
12:23:00 21 What are we holding it next to?
12:23:03 22 Q. Just simply if you can pull up Fig. 7 and
12:23:04 23 put it down and have the table that we just marked
12:23:06 24 from McGovern Exhibit 16 next to it.
12:23:08 25 Yup, you got it. Okay. Yeah. And let's --

12:23:13 1 You have to hold them there.

12:23:15 2 A. Okay.

12:23:19 3 Q. I recognize that this is a hypothetical, but
12:23:21 4 in the event that row 44 in this table, --

12:23:28 5 A. Uh-huh.

12:23:29 6 Q. -- if that infection had actually occurred
12:23:31 7 in September of 2008, that would be in the Bair Hugger
12:23:35 8 period; correct?

12:23:37 9 A. Yes. Yeah.

12:23:39 10 Q. Okay. Have you ever created a graph like
12:23:45 11 Fig. 7 before?

12:23:47 12 MR. GORDON: Object to the form of the
12:23:48 13 question.

12:23:49 14 A. No.

12:23:49 15 Q. Okay. But you understand that the X axis is
12:23:53 16 a range of dates and the Y axis is the percent of
12:23:56 17 infection; correct?

12:23:57 18 A. Well it -- it depends on which axis you're
12:24:01 19 looking at. It's the number -- it's -- there's a --

12:24:06 20 There is a left and a right axis.

12:24:08 21 Q. Okay. The horizontal line on the bottom of
12:24:14 22 the graph goes from July 2008 to January 2011; right?

12:24:19 23 A. Yes.

12:24:19 24 Q. Okay. And there's a number of data points
12:24:22 25 in this graph and some are on the top and some are on

12:24:29 1 the bottom; correct?

12:24:29 2 A. Yeah.

12:24:30 3 Q. And based on the axis on the right-hand
12:24:32 4 side, those on the bottom designate no infection and
12:24:34 5 those on the top designate infection; correct?

12:24:37 6 A. Correct.

12:24:38 7 Q. And the legend for Fig. 7 notes that the
12:24:40 8 data points have been jittered to avoid overprinting;
12:24:43 9 correct?

12:24:43 10 A. Yes.

12:24:44 11 Q. And my understanding of that is essentially
12:24:46 12 that when you look at the graph, there could be two
12:24:49 13 data points that have similar times, but you don't put
12:24:52 14 them on top of each other because it would just look
12:24:55 15 like one point; is that correct?

12:24:56 16 A. That's right. They're trying to see it. I
12:24:59 17 mean in the Xerox you kind of lose it, but --

12:25:02 18 Q. Okay.

12:25:02 19 A. Yeah. Yeah.

12:25:03 20 Q. And if you were to attempt to re-create this
12:25:11 21 graph --

12:25:12 22 A. Uh-huh?

12:25:13 23 Q. -- in a similar way that you recalculated
12:25:15 24 the data in the study, because each jittered data
12:25:18 25 point is specific to a date, --

12:25:22 1 A. Yes.

12:25:22 2 Q. -- that's the manner in which you would have
12:25:23 3 to represent it on the graph; correct?

12:25:28 4 A. My -- my assumption is -- is the jitter has
12:25:31 5 to do with the vertical jitter. They vertically
12:25:34 6 jittered it and not -- so the -- so the date --

12:25:39 7 It appears on the right date, --

12:25:40 8 Q. Yup.

12:25:40 9 A. -- it's just the no-infection point is sort
12:25:45 10 of -- and they jittered both the no infections and the
12:25:51 11 infections. If you notice, they're not all exactly
12:25:52 12 the same points, so they --

12:25:53 13 Q. Well let me put it this way: If you were
12:25:55 14 going to put these dots on this graph, --

12:25:58 15 A. Yeah.

12:25:58 16 Q. -- you wouldn't be able to put them in the
12:26:00 17 right location if you were just saying is it infection
12:26:03 18 or is it non-infection; right? You need to consider
12:26:06 19 the date of the infection or non-infection; right?

12:26:09 20 A. Yeah, it's -- it's by the date, yeah.

12:26:11 21 Q. So the date is the way in which you
12:26:13 22 determine where each infection or non-infection goes
12:26:15 23 on the graph.

12:26:16 24 A. Uh-huh.

12:26:16 25 Q. Okay.

12:26:17 1 THE REPORTER: Your answer? Your answer?

12:26:19 2 THE WITNESS: Yes.

12:26:20 3 Q. Okay. Have you compared this graph to
12:26:27 4 Exhibit 18 in this case but was previously marked as
12:26:30 5 Exhibit 16 by McGovern in -- in the McGovern
12:26:34 6 deposition, have you done this side-by-side comparison
12:26:44 7 before?

12:26:45 8 A. No.

12:26:46 9 Q. Okay. So I'm going to walk you through this
12:26:50 10 and I'll do my best to do it slowly, but the first
12:26:53 11 infection data point that we have in Fig. 7 of the
12:26:56 12 McGovern study appears to be July 2008; correct?
12:27:01 13 Right on the beginning of the study period in the
12:27:04 14 graph of Fig. 7, the first data point in the infection
12:27:12 15 area.

12:27:13 16 A. First infection. I guess so.

12:27:21 17 Q. Yeah. And if you go to McGovern 16, the
12:27:27 18 first infection, which is row six, the date of surgery
12:27:32 19 is July 1st, 2008; correct?

12:27:35 20 A. That's right.

12:27:36 21 Q. So that data point matches this date in
12:27:39 22 McGovern 16; correct?

12:27:40 23 A. Okay.

12:27:41 24 Q. Do you agree?

12:27:42 25 A. Yeah, it seems to be.

12:27:43 1 Q. Yeah. Okay.

12:27:44 2 A. Yeah.

12:27:45 3 Q. Now looking at the table, the next three
12:27:48 4 infections are August 7, 2008, August 12, 2008 and
12:27:53 5 August 13, 2008; correct?

12:27:54 6 A. Yes.

12:27:55 7 Q. In McGovern 16 --

12:27:56 8 Which we've marked as Exhibit 18; correct?

12:27:58 9 A. Right.

12:27:59 10 Q. -- do you see the cluster of three jittered
12:28:03 11 data points in the infection area of this graph?

12:28:06 12 A. Yes.

12:28:06 13 Q. That appears to align with those three
12:28:09 14 infections; correct?

12:28:10 15 A. Yes.

12:28:10 16 Q. Okay. The next cell in McGovern 16 is
12:28:17 17 September 30th, 2008; correct?

12:28:19 18 A. Yeah.

12:28:19 19 Q. And the infection after that is November
12:28:23 20 4th, 2008; correct?

12:28:25 21 In the cell.

12:28:26 22 A. Yeah.

12:28:26 23 Q. Okay. So that's a gap of about a month and
12:28:32 24 five days, September --

12:28:34 25 A. Yeah.

12:28:35 1 Q. -- 30th to November 4th; correct?

12:28:37 2 A. It is, yeah.

12:28:37 3 Q. Okay. Now let's go to the graph. There are
12:28:40 4 two points in a horizontal line virtually on top of
12:28:46 5 each other; correct?

12:28:47 6 A. Yeah.

12:28:48 7 Q. One of those points must be the September
12:28:51 8 30th data point; correct? Because that's the next
12:28:54 9 infection in the table and that's the next infection
12:28:56 10 reported in the graph.

12:28:59 11 A. It could be. I mean it's -- now you're
12:29:02 12 sort of --

12:29:03 13 Q. Well I mean it --

12:29:06 14 A. It's hard to tell. The -- the axis is so
12:29:08 15 rough it's a little hard to tell exactly, but it seems
12:29:11 16 plausible.

12:29:12 17 Q. I mean if the prior three infections are the
12:29:14 18 cluster of three, which are all August infections, --

12:29:16 19 A. Yeah.

12:29:17 20 Q. -- the next data point must be September,
12:29:20 21 correct, and that's the next infection in the McGovern
12:29:22 22 16 Excel file.

12:29:24 23 A. It could be, yeah.

12:29:25 24 Q. You're saying that McGovern 16 is the final
12:29:29 25 data set; correct?

12:29:30 1 A. I didn't say that. I --

12:29:32 2 Q. So you don't know that McGovern 16 is the
12:29:34 3 final data set.

12:29:35 4 A. No, I don't.

12:29:36 5 Q. Okay.

12:29:37 6 A. But I mean it seems plausible.

12:29:40 7 MR. GORDON: Counsel, counsel --

12:29:40 8 A. It's hard to sort of compare here because
12:29:42 9 this axis is -- you know, the cut points are --

12:29:45 10 Q. Yeah.

12:29:45 11 A. -- six months --

12:29:46 12 Q. I understand. I just wanted to clarify
12:29:48 13 that.

12:29:48 14 A. Yeah.

12:29:49 15 MR. GORDON: Counsel, I just want -- want to
12:29:52 16 let you know I have e-mailed to you and Ms. Conlin the
12:29:55 17 Augustine Bates number 0005277 --

12:29:58 18 MR. SACCHET: I know.

12:29:59 19 MR. GORDON: -- that seems to have been
12:30:00 20 missing in the copy which you -- you marked as Exhibit
12:30:04 21 14.

12:30:04 22 MR. SACCHET: Okay.

12:30:05 23 MR. GORDON: I don't know if it's a
12:30:07 24 photocopy error or whatever, but anyway, you do have
12:30:09 25 access to it. I can call it up on my iPad if you want

12:30:15 1 to look at it.

12:30:15 2 MR. SACCHET: I'm not -- I'm not there right
12:30:15 3 now, but I appreciate it, Mr. Gordon.

12:30:17 4 MR. GORDON: But in fairness, there are no
12:30:20 5 infections listed on that.

12:30:23 6 MR. SACCHET: I appreciate your testimony.

12:30:23 7 MR. GORDON: Well it stands in contrast to
12:30:26 8 you giving him an exhibit missing a page and implying
12:30:26 9 that there was something on that page that maybe, you
12:30:29 10 know, was a September 15th, 2008 --

12:30:31 11 MR. SACCHET: I'm talking about McGovern 16
12:30:32 12 right now.

12:30:33 13 MR. GORDON: I -- I was --

12:30:35 14 No, you were talking about --

12:30:36 15 MR. SACCHET: I wasn't talking at all about
12:30:37 16 this.

12:30:37 17 MR. GORDON: But -- but you set this whole
12:30:39 18 thing up with a missing page --

12:30:40 19 MR. SACCHET: That's how it was produced.

12:30:41 20 MR. GORDON: I don't know if that was how it
12:30:44 21 was produced or not.

12:30:45 22 MR. SACCHET: Ask DFT.

23 MR. GORDON: Pardon?

12:30:49 24 MR. SACCHET: Ask DFT if that's the final
12:30:50 25 copy.

12:30:50 1 MR. GORDON: Well then maybe DFT screwed up.

12:30:50 2 I don't know. But you now have --

3 MR. SACCHET: Thank you.

12:30:55 4 MR. GORDON: -- 5277 --

5 MR. SACCHET: Great.

12:30:55 6 MR. GORDON: -- in your e-mail and it shows

12:30:56 7 no infection.

12:30:57 8 MR. SACCHET: I'll note for the record the

12:30:58 9 two-minute soliloquy by Mr. Gordon as a speaking

12:31:02 10 objection that should be not raised in any deposition

12:31:06 11 of an expert witness in this litigation.

12:31:06 12 Q. Back to McGovern 16 -- which is actually the

12:31:09 13 document that we were speaking about, not Albrecht

12:31:13 14 Exhibit 10 -- you stated you don't know whether

12:31:15 15 McGovern 16 is the final data set, but I want to draw

12:31:18 16 your attention back to the graph, and there are two

12:31:20 17 dots there; correct?

12:31:21 18 A. Right.

12:31:21 19 Q. And they're on top of each other; correct?

12:31:23 20 A. Yes.

12:31:24 21 Q. And if the infection cell in the McGovern

12:31:34 22 table was from 9/30/2009 and that's the next

12:31:39 23 infection, the second data point in the graph should

12:31:43 24 be from a similar time period; correct?

12:31:47 25 A. So where are you now?

12:31:48 1 Q. Okay. So I'm still on the one we were
12:31:50 2 talking about, before I was interrupted about a
12:31:52 3 different exhibit, which is row 10 with the September
12:31:56 4 30th, 2008 infection. Do you see that?

12:31:59 5 A. Right. Uh-huh.

12:32:00 6 Q. Okay. And the next infection isn't until
12:32:03 7 November 4th, 2008; correct?

12:32:04 8 A. That's right.

12:32:05 9 Q. And that's about a month-long gap; right?

12:32:07 10 A. Right.

12:32:08 11 Q. But in the graph we have two dots --

12:32:10 12 A. Yeah.

12:32:11 13 Q. -- right on top of each other, one of which
12:32:14 14 you said is plausibly the September 30th, 2008
12:32:19 15 infection; correct?

12:32:30 16 A. Septem --

12:32:36 17 You're -- you're -- you're talking about
12:32:39 18 number 10?

12:32:40 19 Q. Yup. It's September 30th, 2008; correct?

12:32:43 20 A. It's September 30. Okay.

12:32:45 21 Q. Okay.

12:32:45 22 A. So that's one of the --

12:32:46 23 Q. That's one of those two.

12:32:48 24 A. -- two.

12:32:48 25 Q. Yeah.

12:32:49 1 A. Okay.

12:32:49 2 Q. And the next infection is not until November

12:32:52 3 4th --

12:32:53 4 A. Yeah.

12:32:53 5 Q. -- in McGovern 16; correct?

12:32:55 6 A. Right.

12:32:55 7 Q. And the one after that's November 7th --

12:32:58 8 A. Yeah.

12:32:58 9 Q. -- and the one after that's November 18th;

12:33:00 10 right?

12:33:00 11 A. Right.

12:33:01 12 Q. Do you see the cluster of three data

12:33:03 13 points --

12:33:04 14 A. Yeah.

12:33:05 15 Q. -- after the two?

12:33:06 16 A. Yes.

12:33:06 17 Q. Those are presumably the November cluster of

12:33:10 18 infections; correct?

12:33:11 19 MR. GORDON: Object to the form of the

12:33:12 20 question, lack of foundation.

12:33:13 21 A. I don't know for sure. It --

12:33:17 22 Q. It appears to be.

12:33:18 23 A. It's plausible.

12:33:19 24 Q. Okay. What is the second date -- the second

12:33:24 25 dot in between the cluster of three on the right and

12:33:26 1 the cluster of three on the left that's paired with
12:33:29 2 the September 30th, 2008 infection?

12:33:30 3 A. I don't know.

12:33:31 4 MR. GORDON: Object to the form of the
12:33:32 5 question.

12:33:32 6 Q. It's not in the McGovern 16 table; is it?

12:33:34 7 MR. GORDON: Lack of foundation.

12:33:35 8 A. I -- I don't know what formed this graph. I
12:33:39 9 don't -- I mean --

12:33:40 10 Q. This is the graph that's reported in the
12:33:41 11 published study; correct?

12:33:43 12 A. It is a graph in the -- in the published
12:33:45 13 study, --

12:33:46 14 Q. Yeah. I mean --

12:33:47 15 A. -- but the data that went -- that formed
12:33:49 16 this graph I do not -- I don't know that I've seen.
12:33:52 17 It doesn't seem to be this table.

12:33:54 18 Q. Yeah. So it's -- this --

12:33:55 19 This jittered data point is not in McGovern
12:33:59 20 16.

12:33:59 21 A. It doesn't appear to be.

12:34:00 22 Q. And this jit -- jittered data point is in
12:34:03 23 2008.

12:34:06 24 A. It --

12:34:08 25 Yeah, it does seem to be in 2008.

12:34:11 1 Q. That's during the Bair Hugger warming
12:34:13 2 period; correct?

12:34:14 3 A. Uh-huh.

12:34:14 4 Q. So there appears to be an additional
12:34:16 5 jittered data point in the 2008 Bair Hugger period
12:34:19 6 that is not reflected on the McGovern 16 --

12:34:22 7 A. Yeah. Yeah.

12:34:23 8 Q. -- file.

12:34:24 9 A. Yeah.

12:34:27 10 MR. GORDON: Object to the form of the
12:34:28 11 question, lack of foundation.

12:34:36 12 Q. And if you take away cell 44 for the sake of
12:34:41 13 argument and you add in the data point that we just
12:34:45 14 discussed, which is in the Bair Hugger period from
12:34:46 15 2008, that gives you 32 infections.

12:34:50 16 MR. GORDON: Object to the form of the
12:34:51 17 question, lack of foundation, in -- incomplete
12:34:56 18 hypothetical.

12:34:59 19 A. So I don't under --

12:35:03 20 Q. I can break it down further if you want.

12:35:05 21 A. Yeah. What exactly are you proposing?

12:35:08 22 Q. Okay. So in your report you say cell 44 was
12:35:11 23 miscoded to be --

12:35:13 24 A. Yeah.

12:35:14 25 Q. -- a forced-air warming infection because

12:35:16 1 the date of infection -- or date of operation was

12:35:18 2 September 15, 2010; right?

12:35:19 3 A. Yes.

12:35:20 4 Q. So if we just take that off the table, we're

12:35:23 5 down to the 31 infections that you assume in your

12:35:26 6 report; correct?

12:35:28 7 A. Yes.

12:35:29 8 Q. Okay. And this jittered data point in 2008

12:35:35 9 is not reflected in McGovern 16. That's what you just

12:35:38 10 testified to.

12:35:38 11 A. It doesn't seem to be.

12:35:39 12 Q. Okay. If we add that data point into this

12:35:42 13 graph, there are 32 infections.

12:35:44 14 A. Okay. Yes.

12:35:45 15 Q. Thank you.

12:35:47 16 MR. SACCHET: We'll take a break.

12:35:49 17 THE REPORTER: Off the record, please.

12:35:51 18 (Luncheon recess taken.)

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13:27:18 1 AFTERNOON SESSION

13:29:08 2 BY MR. SACCHET:

13:29:10 3 Q. Dr. Holford, I should ask, do you prefer
13:29:14 4 going by doctor or professor?

13:29:16 5 A. Professor is fine. Either one.

13:29:17 6 Q. Okay. In your report on page two you also
13:29:24 7 reference the testimony of Dr. Reed; correct?

13:29:26 8 A. Yes.

13:29:27 9 Q. And you state that the published McGovern
13:29:34 10 analysis may have been in error in light of that
13:29:36 11 testimony; correct?

13:29:37 12 A. Yes.

13:29:38 13 Q. And that testimony suggested that there may
13:29:41 14 have been an additional infection both in the Bair
13:29:44 15 Hugger arm and in the Hot Dog arm; correct?

13:29:47 16 A. That's correct.

13:29:48 17 Q. And you also perform a calculation in
13:29:51 18 footnote one of your report that states, "Even if one
13:29:54 19 assumes that Dr. Reed's recollection in his deposition
13:29:59 20 was correct (that there was one additional infection
13:30:01 21 in each group), the odds ratio is nevertheless
13:30:04 22 markedly different than reported in the published
13:30:07 23 paper," and you go on to note that the odds ratio
13:30:09 24 would be 2.86 with a significant p-value of .0356;
13:30:13 25 correct?

13:30:13 1 A. That's correct.

13:30:15 2 Q. Do you have any reason for not relying on
13:30:20 3 Dr. Reed's recollection of one additional infection in
13:30:23 4 each arm versus the Albrecht Exhibit 10 and McGovern
13:30:28 5 Exhibit 16?

13:30:29 6 A. No. I was just taking what --

13:30:33 7 You know, it's just based on what he said --

13:30:35 8 Q. You would agree that --

13:30:37 9 A. -- in his deposition.

13:30:40 10 Q. Are you finished?

13:30:41 11 A. Yes.

13:30:41 12 Q. You would agree that the calculations that
13:30:43 13 you have performed that are within your report rely on
13:30:48 14 McGovern 16 and Albrecht Exhibit 10; correct?

13:30:51 15 A. I think all of the rest of the calculations,
13:30:55 16 other than footnote one, are based on 10 and 16.

13:31:00 17 Q. And you recognize that Mr. Reed's testimony
13:31:04 18 and the cal -- and the calculation you performed based
13:31:06 19 on that testimony has a higher odds ratio of 2.86 than
13:31:11 20 the 2.76 that you used throughout the report, which
13:31:14 21 are based on Albrecht 10 and McGovern 16.

13:31:17 22 A. That's right.

13:31:17 23 Q. So it's possible that in fact the OR of 2.86
13:31:23 24 could be the actual odds ratio of the study.

13:31:25 25 A. Yes. There seems to be some error in the

13:31:28 1 tabulation in the -- in the paper is what -- what
13:31:36 2 seems to be implied by this testimony of, you know,
13:31:39 3 Reed and Albright and -- and whatever, so I'm trying
13:31:43 4 to sort out as best I can what that error is.

13:31:46 5 Q. And you would agree that the calculation you
13:31:49 6 performed as to Mr. Reed's testimony contradicts the
13:31:53 7 calculation you performed with respect to the McGovern
13:31:55 8 Exhibit 16 and Albrecht Exhibit 10 data; correct?

13:31:59 9 A. It -- it is different, yes.

13:32:00 10 Q. And the Reed calculation results in a
13:32:03 11 significant p-value; correct?

13:32:05 12 A. That's right.

13:32:09 13 Q. To be specific, the calculation on page two
13:32:13 14 of your report where you derive a p-value -- or an
13:32:17 15 odds ratio of 2.76 derives from McGovern Exhibit 16
13:32:21 16 and Albrecht Exhibit 10; correct?

13:32:24 17 A. That's correct.

13:32:25 18 Q. To also be clear, the time trend data which
13:32:29 19 you discuss on page four of your report also derives
13:32:32 20 from Albrecht Exhibit 10 and McGovern Exhibit 16;
13:32:35 21 correct?

13:32:35 22 A. That's correct.

13:32:37 23 Q. The reanalysis of the Jensen data that you
13:32:41 24 performed on page five of your report also depends on
13:32:45 25 the veracity of McGovern Exhibit 16 and Albrecht

13:32:48 1 Exhibit 10.

13:32:48 2 A. That's correct.

13:32:49 3 Q. The calculation you performed on page four
13:32:52 4 with respect to controlling for the thromboprophylaxis
13:32:57 5 also derives from Albrecht Exhibit 10 and McGovern
13:33:00 6 Exhibit 16; correct?

13:33:01 7 A. Correct.

13:33:02 8 MR. GORDON: Object to the form of the
13:33:03 9 question.

13:33:04 10 Q. The calculation you performed also on page
13:33:06 11 six with respect to controlling for the antibiotic
13:33:09 12 derives from the data in McGovern Exhibit 16 and
13:33:12 13 Albrecht Exhibit 10; correct?

13:33:13 14 A. Yes.

13:33:14 15 Q. And finally, with respect to the conclusions
13:33:17 16 that you offer in terms of causal inferences in the
13:33:20 17 latter parts of your report, those calculations so too
13:33:24 18 rely on the data from McGovern Exhibit 16 and Albrecht
13:33:26 19 Exhibit 10; correct?

13:33:28 20 A. Yes. They're basically referring to the
13:33:32 21 analyses I did in the previous sections.

13:33:35 22 Q. So all those calculations depend on the
13:33:37 23 veracity of Albrecht Exhibit 10 and McGovern Exhibit
13:33:40 24 16.

13:33:43 25 A. Yes, I think that's right. Yeah.

13:33:45 1 Q. I'm going to change gears a little bit now
13:33:53 2 and talk about the particular tests that --
13:33:56 3 statistical tests that were used both in the McGovern
13:33:58 4 study and in your report.

13:34:00 5 A. Uh-huh.

13:34:01 6 Q. With respect to -- with respect to reviewing
13:34:07 7 the McGovern study, the authors used chi-squared;
13:34:11 8 correct?

13:34:11 9 A. That's correct.

13:34:11 10 Q. And their calculation, when using the data
13:34:14 11 reported in this study, resulted in a p-value of .024;
13:34:21 12 correct?

13:34:21 13 A. I think that's correct. That sounds --
13:34:23 14 sounds right. I'd have to look back at the paper, but
13:34:25 15 I think it's right.

13:34:26 16 Q. Okay. It is, but --

13:34:28 17 And based on the chi-squared on that data
13:34:33 18 set, the odds ratio is 3.8.

13:34:35 19 A. That's right.

13:34:36 20 Q. And the confidence interval was 1.2 to 12.5;
13:34:39 21 correct?

13:34:39 22 A. That's right.

13:34:40 23 Q. Now in your report you also apply Fisher's
13:34:45 24 exact test to the data that was reported in the
13:34:49 25 McGovern study; correct?

13:34:49 1 A. Yes, I did.

13:34:50 2 Q. And when you perform that calculation, you
13:34:53 3 also find a significant p-value; correct?

13:34:55 4 A. That's correct.

13:34:56 5 Q. And the p-value with respect to the reported
13:34:58 6 data using Fisher's is .0176; correct?

13:35:05 7 A. That's correct. Yeah.

13:35:07 8 Q. So I've been trying to figure this out
13:35:09 9 because I know that Fisher's exact is generally a more
13:35:13 10 conservative test, but in this particular instance
13:35:16 11 chi-squared had a less significant p-value but which
13:35:20 12 was still significant than under Fisher. Is that --

13:35:23 13 And I can back up. The p-value using X
13:35:26 14 chi-squared was .024 in the study; correct?

13:35:29 15 A. That's right.

13:35:31 16 Q. And then when you did Fisher's on the -- the
13:35:35 17 data reported in this study, you got a p-value of
13:35:39 18 .07 -- .0176.

13:35:41 19 A. Yeah.

13:35:41 20 Q. So in that particular instance the p-value
13:35:45 21 actually increased by using chi-squared; correct?

13:35:49 22 A. It -- it did. The Fisher's -- but I --

13:35:53 23 The premise I think of your question was
13:35:55 24 that Fisher's is conservative.

13:35:57 25 Q. And we can get to that later.

13:35:59 1 A. Oh, okay. I would disagree with that --

2 Q. Okay.

13:36:02 3 A. -- characterization.

13:36:03 4 Q. But with respect to what we're talking about

13:36:06 5 now, the p-val -- p-value actually went down when

13:36:09 6 using Fisher's as opposed to chi-squared.

13:36:12 7 A. That's correct.

13:36:13 8 Q. If the authors had truly wanted to cherry

13:36:16 9 pick a p-value, they could have employed Fisher's and

13:36:18 10 had a more significant p-value; correct?

13:36:21 11 A. They -- they could have, yes.

13:36:22 12 Q. And they did not.

13:36:23 13 A. No.

13:36:25 14 Q. When using Fisher's on the original data set

13:36:29 15 reported in the McGovern study, the OR, instead of

13:36:33 16 being 3.8, is 3.79, correct, so virtually identical?

13:36:37 17 A. Yeah, uh-huh. I assume it just depends on

13:36:42 18 how much --

13:36:42 19 What you're rounding is I think the

13:36:44 20 difference.

13:36:44 21 Q. Okay. Now going back to the data that you

13:36:50 22 used in your report; namely, the four infections in

13:36:53 23 the Hot Dog period and the 31 infections in the Bair

13:36:56 24 Hugger period, --

13:36:57 25 A. Uh-huh.

13:36:57 1 Q. -- you also used that data and calculated
13:37:02 2 p-values and odds ratios using chi-squared; correct?

13:37:05 3 A. For the analysis on --

13:37:14 4 Let's see, where is it?

13:37:15 5 Q. Page two.

13:37:17 6 A. Page two. I mean the p-value I give there
13:37:24 7 is -- is actually the F -- I'm sorry, Fisher's --
13:37:29 8 Fisher's exact.

13:37:31 9 Q. Did you report a p-value of .0480 when using
13:37:35 10 chi-squared --

13:37:35 11 A. Oh, I'm sorry.

13:37:36 12 Q. -- on the remixed data set?

13:37:39 13 A. That's true. I also -- I also did the
13:37:40 14 chi-square in the --

13:37:42 15 Yeah, it got a little lower.

13:37:45 16 Q. And you note that it is just below the
13:37:47 17 threshold of statistical significance; correct?

13:37:51 18 A. That's right.

13:37:51 19 Q. It's the same p-value that was reported in
13:37:54 20 the Jensen study which you cited in your reference
13:37:57 21 material; correct?

13:37:58 22 MR. GORDON: Which -- which is?

13:37:59 23 THE WITNESS: Which --

13:37:59 24 MR. SACCHET: The Jensen study on control --

13:38:01 25 MR. GORDON: No, which -- which of the

13:38:02 1 p-values, the chi-square one or the --

13:38:04 2 Q. The chi-squared P&L value of .0480 --

13:38:09 3 A. Okay.

13:38:09 4 Q. -- is the same p-value that Jensen et al
13:38:14 5 reported in their study, which evaluated whether there
13:38:17 6 was an increased risk of infection between using
13:38:22 7 Xarelto versus using a low-molecular-weight heparin.

13:38:29 8 A. I don't remember what they -- exactly what
13:38:32 9 they reported.

13:38:46 10 (Exhibit 19 was marked for
13:38:48 11 identification.)

13:38:48 12 BY MR. SACCHET:

13:38:51 13 Q. Exhibit 19 is entitled "Return to theatre
13:38:56 14 following total hip and knee replacement, before and
13:38:59 15 after the introduction of rivaroxaban," by Jensen et
13:39:04 16 al; correct?

13:39:04 17 A. Yes. And where are you --

13:39:05 18 Q. In the abstract on the first page in the
13:39:08 19 second paragraph, the statement there says, "Nine
13:39:12 20 patients in the control (tinzaparin) group returned to
13:39:15 21 theatre with wound complications within 30 days,
13:39:18 22 compared with 22 patients in the rivaroxaban group.
13:39:22 23 This increase was statistically significant (at p
13:39:25 24 equals 0.048)."

13:39:27 25 MR. GORDON: Counsel, I think your earlier

13:39:28 1 question was that they reported a statistically
13:39:33 2 significant difference in infection rates at that
13:39:35 3 p-value, that's -- and that's not what they did.

13:39:37 4 Q. I'll rephrase my question.

13:39:38 5 A. They didn't -- yeah.

13:39:39 6 Q. I'll rephrase the question.

13:39:40 7 Is the p-value that's reported in the
13:39:42 8 abstract of the Jensen study 0.048?

13:39:45 9 I recognize that the 8 is difficult to read.

13:39:48 10 A. It's hard to see if it's an 8 or a 6, but
13:39:51 11 yeah, it's -- it's less than .05.

13:39:53 12 Q. Okay. And the authors there deemed it to be
13:39:55 13 statistically significant.

13:39:57 14 MR. GORDON: What --

13:39:57 15 A. That's right.

13:39:58 16 Q. They made no mention that it was marginally
13:40:01 17 significant or close to the threshold of significance.

13:40:03 18 A. They didn't say.

13:40:09 19 Q. So whether or not one uses the original data
13:40:14 20 as reported in the McGovern study or the reanalyzed
13:40:18 21 data that you provide in your report, --

13:40:19 22 A. Uh-huh?

13:40:20 23 Q. -- using X-squared results in a significant
13:40:23 24 p-value; correct? Under .05.

13:40:26 25 A. That's right, yeah.

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13:40:30 1 Q. You go on in your report, however, to state
13:40:39 2 that Fisher's exact test is the more appropriate test
13:40:42 3 in this circumstance; correct, professor?

13:40:44 4 A. Uh-huh.

13:40:45 5 THE REPORTER: Your answer?

13:40:46 6 THE WITNESS: Yes. Yeah.

13:40:48 7 Q. Notwithstanding your view as to the
13:40:52 8 propriety of Fisher's versus chi-squared, you'd
13:40:55 9 agree that there is a long-standing debate about
13:40:59 10 whether to use Fisher's or chi-squared based on
13:41:03 11 certain determinants such as sample size and incidence
13:41:07 12 of an outcome; correct?

13:41:07 13 MR. GORDON: Object to the form of the
13:41:09 14 question.

13:41:10 15 A. I -- I don't know that there's a debate. I
13:41:12 16 think it's -- Fisher's is -- is --

13:41:19 17 I mean chi-square de -- derives from a -- a
13:41:25 18 mathematical approximation for what the distribution
13:41:29 19 is for the statistic that you're looking at, and so
13:41:34 20 it's relying on that approximation. The approximation
13:41:40 21 works quite well if the sample size is large, it works
13:41:44 22 more poorly as the -- as the expected number of cases
13:41:49 23 becomes smaller and smaller. And so it -- it's in --

13:41:57 24 In contrast, the Fisher's exact test is not
13:42:03 25 an approximation, it's an exact calculation.

13:42:09 1 That's -- so because -- depending on the --

13:42:13 2 You know, if results that go into that

13:42:16 3 are -- are appropriate, then you're getting a -- an

13:42:19 4 actual p-value and not an approximate p-value, which

13:42:22 5 is what the chi-square is -- chi-square is yielding,

13:42:26 6 so in that respect I don't know that there's a huge

13:42:36 7 debate or controversy about that. The only --

13:42:42 8 Chi-square is a lot easier to compute, and

13:42:45 9 so when you're doing it by hand it's a lot more work

13:42:49 10 to do Fisher's, but if you're just typing in the table

13:42:54 11 into a -- into a computer, which of course is what we

13:42:56 12 have now, it's pretty straightforward to do.

13:42:59 13 Q. But you're aware that other statisticians

13:43:02 14 have criticized Fisher's exact test as being overly

13:43:05 15 conservative; are you not?

13:43:07 16 A. I'm not sure it's particularly overly --

13:43:10 17 overly conservative.

13:43:12 18 Q. Not in your view. I'm saying are you --

13:43:16 19 A. Yes.

13:43:14 20 Q. -- aware of other statisticians who have

13:43:17 21 criticized Fisher's exact test as being overly

13:43:19 22 conservative?

13:43:20 23 A. Some might argue that, yeah.

13:43:23 24 Q. So there is a --

13:43:24 25 A. It -- it's not -- but it's not uniformly --

1 the --

13:43:27 2 The direction does not go one way. I mean

13:43:32 3 as you -- as you --

13:43:34 4 Q. Yeah.

13:43:35 5 A. -- just pointed out, --

13:43:36 6 Q. It can go down.

13:43:38 7 A. -- Fisher's can -- can be greater or less,

13:43:41 8 and the context in which I used Fisher's is that I

13:43:44 9 think it's more accurate when the numbers are small

13:43:48 10 and -- as in these tables.

13:43:50 11 Q. I'll get to that in a moment. I just want

13:43:53 12 to pin down --

13:43:53 13 A. Sure.

13:43:54 14 Q. -- that there are statisticians who have

13:43:57 15 criticized Fisher's exact test as being overly

13:43:59 16 conservative.

13:44:00 17 A. Okay.

13:44:00 18 Q. You agree.

13:44:02 19 A. There may be a few that -- that don't agree,

13:44:05 20 but --

13:44:06 21 Q. Do you know Professor Douglas Liddell of

13:44:08 22 McGill University?

13:44:09 23 A. I know of him, yeah.

13:44:10 24 Q. Have you read "Practical Tests of 2 x 2

13:44:15 25 Contingency Tables" that was published in The

13:44:17 1 Statistician in 1976?

13:44:19 2 A. Ooh, I don't know. I may have at some
13:44:21 3 point. I don't remember.

13:44:22 4 Q. So you're not aware one way or the other
13:44:24 5 whether Professor Liddell said Fisher's exact test was
13:44:29 6 overly conservatively in that article.

13:44:31 7 A. He may well have. I'm not -- just -- I just
13:44:34 8 don't recall that paper off the top of my head.

13:44:35 9 Q. He's an expert in the field; correct?

13:44:37 10 A. Yeah, uh-huh.

13:44:38 11 Q. I assume you're also aware of Professor --
13:44:39 12 or Dr. Joseph Berkson from the Mayo Clinic in
13:44:40 13 Minneapolis.

13:44:41 14 A. Yes.

13:44:41 15 Q. He was the head of biometry at the Mayo
13:44:44 16 Clinic?

13:44:44 17 A. Yes.

13:44:44 18 Q. Same field as you; right?

13:44:47 19 A. That's right.

13:44:47 20 Q. And the Mayo Clinic is a well-respected
13:44:50 21 institution; correct?

13:44:51 22 A. Yes.

13:44:51 23 Q. You respect Professor Berkson's views?

13:44:56 24 A. Basically, yeah. I mean, yeah, he was there
13:44:59 25 a while ago.

13:45:00 1 Q. Have you read his article and his praises of
13:45:03 2 the exact test?

13:45:05 3 A. I -- I may have. I don't remember. When
13:45:07 4 was that published?

13:45:08 5 Q. I actually don't know when it was published.
13:45:10 6 I think it was in the '80s.

13:45:11 7 A. Okay.

13:45:12 8 Q. But are you aware of his conclusion that the
13:45:15 9 use of the term "Fisher's exact" is simply just a
13:45:18 10 sobriquet because it derives from R. A. Fisher's
13:45:22 11 creation of the test?

13:45:23 12 A. That's -- that's a --

13:45:25 13 Yeah. Fisher I know derived the test and --

13:45:28 14 Q. But the use of the word "exact" really -- I
13:45:32 15 mean is a sobriquet.

13:45:35 16 A. Well the --

13:45:37 17 I suppose. I mean it's exact if -- if --
13:45:40 18 depending on the results that Fisher -- that form the
13:45:46 19 basis for -- for Fisher's derivation. I mean it's
13:45:49 20 a --

13:45:50 21 It is based on a hypergeometric distribution
13:45:53 22 and it's exact from that. The chi-square by
13:45:57 23 comparison is based on the idea that -- you know, that
13:46:03 24 it becomes approximately a chi-square distribution, so
13:46:06 25 there's an approximation involved with that. And why

13:46:09 1 he called it an exact test is because there was not an
13:46:13 2 approximation involved.

13:46:14 3 Q. Do you disagree with Professor Berkson's
13:46:17 4 view that the problem with Fisher's is that you're
13:46:19 5 essentially combining discrete statistics with fixed
13:46:23 6 significance levels -- significance levels?

13:46:25 7 A. Well I think -- yeah. I mean that -- that
13:46:29 8 is a problem. That is, I think, a different --
13:46:33 9 different problem because it is discrete. If you're
13:46:37 10 comparing at exactly the .05 level, the discrete
13:46:43 11 probabilities that it can take may not correspond to
13:46:47 12 exactly the .05.

13:46:48 13 Q. Yeah.

13:46:49 14 A. So it may go from .04 to .06, so you'd
13:46:54 15 reject the .04 but not the .06.

13:46:57 16 Q. That's a problem.

13:46:59 17 A. There's a space in there, so there is --
13:47:01 18 there is a little bit of an ambiguity there. It
13:47:06 19 may --

13:47:07 20 Well not it's ambiguous. It's either less
13:47:10 21 or not.

13:47:10 22 Q. Yeah.

13:47:10 23 A. But there is -- there is a bit of a -- of
13:47:13 24 a -- of a problem of comparing exactly because it's
13:47:16 25 not a continuous distribution.

13:47:18 1 Q. And that's a problem with Fisher's test.

13:47:21 2 A. I don't know if it's a problem. It's --

13:47:23 3 Q. It's a ramification of the test.

13:47:24 4 A. It's an issue, yes.

13:47:25 5 Q. Okay. And in light of that, according to

13:47:27 6 Berkson, Fisher's may result in the rejection of

13:47:32 7 p-values that are very close to significant but

13:47:36 8 ultimately render them non-significant.

13:47:39 9 A. That's right. Yeah. You could -- you could

13:47:41 10 have that.

13:47:42 11 Q. So in this --

13:47:43 12 A. So in the example I just stated, I mean it

13:47:45 13 could be if that's the situation involved, you would

13:47:50 14 only reject at the .04, and so there's that little --

13:47:53 15 Q. Yeah.

13:47:54 16 A. -- gap.

13:47:55 17 Q. Isn't that precisely the circumstance here,

13:47:58 18 because when you analyzed the remixed data using

13:48:04 19 chi-squared, you calculated a p-value of 0.0480;

13:48:11 20 correct?

13:48:11 21 A. I guess that's what it was, yeah.

13:48:13 22 Q. And then when you used Fisher, it went to

13:48:17 23 0.0507, so it took -- it took a p-value --

13:48:21 24 A. Yes.

13:48:22 25 Q. -- that was significant, just below the

13:48:25 1 traditional threshold of 0.05, and it rendered it non-
13:48:28 2 significant using Fisher's. That's exactly what
13:48:31 3 Berkson describes in his article of -- in his praise
13:48:36 4 of the exact test; correct?

13:48:37 5 A. As I say, I don't remember what -- what
13:48:39 6 Berkson -- Berkson's issue was. If that was his
13:48:42 7 issue, that would be an issue, and that, I mean --

13:48:46 8 Q. That's the issue we just talked about when
13:48:48 9 you said --

13:48:49 10 A. Yeah, yeah. That -- that is -- that is an
13:48:51 11 issue --

13:48:51 12 Q. Okay.

13:48:51 13 A. -- associated with that test. I mean any
13:48:54 14 way you cut it, it's very close to the line. Even --
13:48:58 15 even the chi-square was, what, point -- .048.

13:49:03 16 Q. Yeah.

13:49:04 17 A. That's not way out in the wild blue yonder
13:49:08 18 somewhere, that's really -- that is close to the line,
13:49:10 19 too.

13:49:12 20 Q. Agreed.

13:49:12 21 A. They're both, you know, close to the line.

13:49:13 22 Q. But in your conclusions of your report, one
13:49:16 23 of your rationales for concluding that the McGovern
13:49:18 24 study is not valid is because the p-value is not
13:49:21 25 significant; correct?

13:49:21 1 MR. GORDON: Object to the form of the
13:49:22 2 question.

13:49:25 3 A. That the p-value --

13:49:29 4 Well it is what it is.

13:49:31 5 Q. Well on page six of your --

13:49:33 6 A. I mean --

13:49:34 7 Q. -- report in the "Conclusions regarding the
13:49:36 8 McGovern et al. findings" you say, "Reasons why the
13:49:39 9 McGovern et al. conclusions are not valid are:

13:49:42 10 "1." And the very last clause of that
13:49:45 11 number one is, "...which is close but not
13:49:48 12 statistically significant."

13:49:52 13 A. Yes. So that is the difference because it
13:49:54 14 doesn't achieve statistical significance; it's very
13:49:57 15 close to the line.

13:49:59 16 Q. And we just agreed that if you used
13:50:01 17 chi-squared it would be significant.

13:50:05 18 A. Yes.

13:50:05 19 Q. And we also just agreed that one of the
13:50:07 20 issues or ramifications of using Fisher's is that
13:50:12 21 values that are significant, --

13:50:14 22 A. No.

13:50:14 23 Q. -- just below the conventional line of
13:50:16 24 statistical significance, may be deemed non-
13:50:19 25 significant by applying Fisher.

13:50:21 1 A. No, that's not -- that's not what I said.

13:50:24 2 They could be close to the line, but that -- that

13:50:27 3 doesn't mean they're statistically significant. If

13:50:30 4 they're -- if they're not --

13:50:31 5 If they don't cross the line, they're not

13:50:33 6 significant.

13:50:33 7 Q. Okay. So --

13:50:34 8 But I'm going to back up because we just

13:50:36 9 talked about how one ramification of using Fisher's,

13:50:39 10 because there are discrete statistics with fixed

13:50:43 11 significance levels, --

13:50:44 12 A. Yeah.

13:50:44 13 Q. -- that a statistic that is just below the

13:50:47 14 line of statistical significance, in the .04 range --

13:50:50 15 A. Well if it's below .05 --

13:50:53 16 Q. Yes.

13:50:54 17 A. -- it's significant, so don't you mean just

13:50:56 18 above?

13:50:57 19 Q. Well Fisher's would bring it just above;

13:50:59 20 correct?

13:50:59 21 A. Fisher's would bring it above, --

13:51:02 22 Q. Yes.

13:51:03 23 A. -- but there --

13:51:07 24 The problem is is that you can -- there

13:51:10 25 would not be a corresponding table that would give you

13:51:13 1 exactly .05, so that's not to say that, you know, it's
13:51:21 2 not -- it is or isn't significant. It doesn't cross
13:51:24 3 the line, which is the criteria for being
13:51:26 4 statistically significant.

13:51:28 5 Q. Okay. I'm going to try to back up again.

13:51:32 6 Your conclusion here on page six of your
13:51:34 7 report --

13:51:35 8 A. Yeah.

13:51:35 9 Q. -- says that one of the reasons the McGovern
13:51:37 10 study is not valid is because the p-value is close to
13:51:40 11 but not statistically significant; correct?

13:51:43 12 A. That's right. The p-value that I'm talking
13:51:45 13 about --

13:51:46 14 Q. I just want to establish that.

13:51:47 15 A. -- is .05 --

13:51:50 16 Q. 507.

13:51:51 17 A. 507.

13:51:51 18 Q. Correct.

13:51:52 19 A. That's greater than .05.

13:51:53 20 Q. We've also established that when you apply
13:51:56 21 chi-squared to the data derived from Albrecht 10 and
13:51:59 22 McGovern seven -- 16, that the p-value is 0.048;
13:52:03 23 correct?

13:52:03 24 A. That's right.

13:52:04 25 Q. Just below statistical significance.

13:52:06 1 A. That's right.

13:52:07 2 Q. One of Berkson's critiques, whether or not
13:52:10 3 you've read the article, you appeared to agree that
13:52:13 4 there's an issue with combining discrete statistics
13:52:15 5 with fixed significance levels; correct?

13:52:18 6 A. I'm --

13:52:19 7 Q. You said that was a ramification of using
13:52:22 8 Fisher's.

13:52:22 9 A. A ramification, --

13:52:23 10 Q. Yes.

13:52:23 11 A. -- not necessarily a --

13:52:24 12 It's a problem with what you're -- with what
13:52:27 13 you're trying to do. It is an issue with discrete --
13:52:31 14 discrete probability values.

13:52:32 15 Q. And an implication of that is that p-values
13:52:35 16 that would otherwise be nominally significant, just
13:52:39 17 below the conventional limit of .05, would be rendered
13:52:45 18 non-significant above .05; correct?

13:52:47 19 A. No.

13:52:48 20 Q. So you disagree with Joseph Berkson.

13:52:51 21 A. I don't think that's --

13:52:52 22 I doubt that's what he is saying. I mean
13:53:00 23 the premise of what you just said was that the value
13:53:06 24 would be significant. Right? Isn't that what you
13:53:09 25 said?

13:53:09 1 Q. I said if you have a -- for example, a
13:53:11 2 p-value of 0.048, which is significant --
13:53:14 3 A. That is significant, --
13:53:15 4 Q. Yeah.
13:53:16 5 A. -- but it's less than .05. It's not .05.
13:53:21 6 Q. Well it's significant because it's less than
13:53:24 7 .05; correct?
13:53:25 8 A. Exactly.
13:53:26 9 Q. Okay. So I think we might be missing each
13:53:28 10 other.
13:53:29 11 A. So --
13:53:31 12 Q. So --
13:53:32 13 A. So I --
13:53:34 14 How exactly did you say that statement
13:53:36 15 again, --
13:53:36 16 Q. Okay.
13:53:36 17 A. -- which is what my problem is?
13:53:39 18 Q. Okay. So when you apply chi-squared --
13:53:41 19 A. Yeah.
13:53:41 20 Q. -- to the reanalyzed data, we get a p-value
13:53:45 21 of 0.048, correct, which is below --
13:53:47 22 A. That's -- that's an approximate p-value.
13:53:49 23 Q. Yes.
13:53:49 24 A. That approximate p-value is less than .05.
13:53:52 25 Q. And it's statistically significant because

13:53:54 1 it's below --

13:53:55 2 A. It's below.

13:53:56 3 Q. -- 0.05, which is the conventional line for
13:53:59 4 significance.

13:54:00 5 A. That's -- that -- that is one of the -- one
13:54:03 6 of the thoughts used, yes.

13:54:03 7 Q. Yes. When you apply Fisher's, it goes from
13:54:05 8 0.048 to 0.0507; correct?

13:54:09 9 A. That's right.

13:54:09 10 Q. And one of the issues with Fisher's is
13:54:13 11 that it's combining discrete statistics with fixed --

13:54:17 12 A. Yeah.

13:54:18 13 Q. -- significance levels; right?

13:54:19 14 A. Well it has --

13:54:21 15 Q. We said that three times.

13:54:22 16 A. -- significant value, yeah.

13:54:24 17 Q. Okay. And the implication of doing that is
13:54:26 18 what you said earlier where a p-value of .04 could
13:54:32 19 then become non-significant by applying Fisher's.

13:54:35 20 A. No. The .04 doesn't --

13:54:43 21 It's not the .04 is going to this. They're
13:54:47 22 two different -- completely different ways in which
13:54:51 23 these things are computed, so one does not change.

13:54:55 24 Q. Okay. Would you agree that chi-squared is
13:54:59 25 better for larger sample sizes --

13:55:02 1 A. I wouldn't say it's better.

13:55:03 2 Q. -- than Fisher?

13:55:04 3 It's equally as good?

13:55:06 4 A. There -- yeah, for large sample size --

13:55:10 5 Well the results will -- will agree much

13:55:11 6 better as the sample size increases.

13:55:14 7 Q. Is chi-squared better or equally as good as
13:55:17 8 Fisher's when using a well-balanced table?

13:55:21 9 A. "Well-balanced table," what do you mean?

13:55:23 10 Q. I -- I -- I guess two arms that have
13:55:28 11 approximately the same number of data.

13:55:29 12 A. It's --

13:55:32 13 I don't know if it's better or -- better or
13:55:38 14 worse. How much --

13:55:39 15 It depends on the balance. It depends --
13:55:43 16 what's particularly critical is the -- the expected
13:55:48 17 number --

13:55:49 18 Q. Yes. I'm going to go --

13:55:50 19 A. -- in the cell, yeah.

13:55:53 20 Q. I'll get here.

13:55:54 21 But you do say in your report that
13:55:56 22 chi-squared works well for comparing proportions when
13:56:00 23 the sample size is large; right?

13:56:02 24 A. That's right. When the -- when the -- when
13:56:03 25 the numbers in all of the cells of the tables are

13:56:05 1 reasonably large, greater than five is one rule of

13:56:09 2 thumb, --

13:56:09 3 Q. Yeah.

13:56:10 4 A. -- and then -- then it does pretty --

13:56:13 5 pretty --

13:56:14 6 The difference is pretty small.

13:56:15 7 Q. What --

13:56:16 8 So in terms of just talking about

13:56:18 9 population, --

13:56:19 10 A. Uh-huh.

13:56:19 11 Q. -- what is a large population in your view?

13:56:23 12 MR. GORDON: Object to the form -- object to

13:56:27 13 the form of the question.

13:56:27 14 Q. So does it depend on what the expected value

13:56:29 15 would be, or could you determine that, okay, 5,000

13:56:32 16 persons is a large population, or, you know, 2,000 is

13:56:35 17 large or 10 --

13:56:36 18 You know, I'm just trying to understand.

13:56:38 19 Because in your report you say the McGovern population

13:56:41 20 is relatively small, so I'm trying to kind of

13:56:44 21 contrast, well, what's a large population in your

13:56:46 22 view?

13:56:46 23 A. Well it's relatively small because the

13:56:53 24 number of infections in the -- in -- in one of the

13:56:59 25 groups is like, what, three -- three or four depending

13:57:01 1 on which tabulation it is, so it's less than five.

13:57:05 2 Q. So --

13:57:05 3 A. So it's that value --

13:57:07 4 So I mean 5,000 seems like a large

13:57:11 5 population, but if you're looking at an effect that

13:57:15 6 occurs one-tenth of one percent of the time --

13:57:19 7 Q. Uh-huh.

13:57:20 8 A. -- or less than that, then the numbers of

13:57:24 9 infected start getting pretty small.

13:57:26 10 Q. Got it.

13:57:27 11 So do you agree or disagree with this view

13:57:31 12 that you can apply Fisher's or chi-squared based on

13:57:37 13 one option, which are expected values, and another

13:57:40 14 option, which is size of population, just raw

13:57:43 15 population?

13:57:45 16 A. Just raw population I don't think is as

13:57:48 17 critical as -- as values in -- in individual cells.

13:57:53 18 That's -- that's -- that's a much more important --

19 Q. So --

13:57:58 20 A. -- factor than the total size.

13:57:59 21 Q. Do you disagree with The Handbook of

13:58:03 22 Biostatistics which states that "I recommend you use

13:58:06 23 Fisher's exact test when the total sample size is less

13:58:09 24 than a thousand?"

13:58:17 25 A. I have to read the whole entry in the --

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13:58:20 1 But that doesn't sound quite right. I mean

13:58:27 2 I think there would --

13:58:28 3 You could have the total sample size be less

13:58:33 4 than a thousand and if it's -- you know, if the

13:58:37 5 balance among cells is such that the expected values

13:58:43 6 of the fields are reasonably large, chi-square would

13:58:46 7 do reasonably well.

13:58:58 8 (Exhibit 20 was marked for

13:59:00 9 identification.)

13:59:00 10 BY MR. SACCHET:

13:59:05 11 Q. Turning to the last page of the document,

13:59:07 12 professor, the citation is "McDonald, J.H. 2014.

13:59:14 13 Handbook of Biological Statistics (3rd edition)." Do

13:59:18 14 you see that?

13:59:26 15 A. Where is this?

13:59:28 16 Q. On the last -- on the last page in the most

13:59:32 17 full paragraph that's three lines long, the citation

13:59:40 18 says this document may be cited as "McDonald, J.H.

13:59:43 19 2014. Handbook of Biological Statistics (3rd

13:59:46 20 edition)."

13:59:47 21 A. Okay.

13:59:47 22 Q. Do you see that?

13:59:48 23 A. Yeah.

13:59:48 24 Q. Okay. And if you go to the first page of

13:59:51 25 the document --

13:59:53 1 A. Okay.

13:59:55 2 Q. -- there's a "Summary" section of when to
13:59:57 3 use a null hypothesis and how the test works; right?

14:00:00 4 A. Yes.

14:00:00 5 Q. And under the "When to use it," the very
14:00:03 6 last paragraph starts with "Fisher's exact test is
14:00:06 7 more accurate" blah, blah, blah; right? The very --
14:00:10 8 the last paragraph of the --

14:00:13 9 A. Yes.

14:00:14 10 Q. -- section there.

14:00:15 11 A. Yes.

14:00:15 12 Q. The second sentence says, "I recommend you
14:00:17 13 use Fisher's exact test when the total sample size is
14:00:20 14 less than 1000..."

14:00:21 15 A. Okay.

14:00:23 16 Q. So is it wrong to conclude that you don't
14:00:26 17 need to use Fisher's exact test when the sample size
14:00:30 18 is greater than a thousand?

14:00:31 19 MR. GORDON: Object to the form of the
14:00:33 20 question.

14:00:35 21 A. I'm sorry, could you repeat that?

14:00:37 22 Q. So this paragraph is comparing the use of
14:00:39 23 Fisher's exact test to chi-squared in the G test.

14:00:42 24 A. Yes.

14:00:43 25 Q. And this handbook states that you should use

14:00:45 1 Fisher's exact test when the sample size is less than
14:00:49 2 a thousand; correct?

14:00:50 3 A. Yes.

14:00:50 4 Q. Do you disagree with the implication of that
14:00:54 5 statement, which is you don't need to use Fisher's
14:00:58 6 exact test when the sample -- when the sample size is
14:01:00 7 greater than a thousand?

14:01:01 8 A. I don't think it says that.

14:01:02 9 Q. What would it mean when it says it
14:01:04 10 recommends to use it when it's less than a thousand?
14:01:06 11 That doesn't mean that it's not --

14:01:08 12 A. It doesn't -- it doesn't say what to do when
14:01:11 13 it's greater than a thousand.

14:01:12 14 Q. Okay. But it's your view that you don't
14:01:14 15 apply chi-squared if it's greater than a thousand just
14:01:19 16 as a raw number?

14:01:19 17 A. I don't think it's particularly --
14:01:20 18 It doesn't say whether or not -- or not. I
14:01:24 19 mean if it's greater than a thousand, there are
14:01:27 20 circumstances where I think it's still better to use.

14:01:28 21 Q. You've applied chi-squared in populations of
14:01:32 22 less than a thousand; haven't you?

14:01:33 23 A. I probably have, yeah.

14:01:35 24 Q. Is there a reason why in those articles you
14:01:37 25 did so but in this report you don't?

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14:01:40 1 A. Well because the numbers were -- in the
14:01:43 2 cells were bigger.

14:01:44 3 Q. Okay. I just want to make sure that that's
14:01:48 4 true. So --

14:01:51 5 A. Well I don't if I --

14:01:53 6 I've published a lot of papers, I don't know
14:01:56 7 if I made a mistake in some, but that's generally what
14:01:59 8 I do. If it's -- if it's a small number, I'll do the
14:02:02 9 exact.

14:02:50 10 (Exhibit 21 was marked for
14:02:51 11 identification.)

14:02:52 12 BY MR. SACCHET:

14:02:55 13 Q. Did you author this study, professor?

14:02:58 14 A. I am one of the authors on this study.

14:03:00 15 Q. Okay.

14:03:02 16 A. Fairly far down the list. Okay.

14:03:06 17 Q. The last paragraph in the right-hand column
14:03:09 18 on the first page says that "Of the initial 1,002
14:03:16 19 infants enrolled, 880 were included..." Do you see
14:03:19 20 that?

14:03:19 21 A. Yes.

14:03:20 22 Q. If you turn to internal page 785, --

14:03:28 23 A. Yes.

14:03:30 24 Q. -- the last paragraph in the left-hand
14:03:34 25 column starts "A major strength..." Do you see that?

14:03:39 1 A. Yes.

14:03:39 2 Q. "A major strength of our study is that we
14:03:42 3 collected extensive respiratory symptom data, material
14:03:45 4 asthma allergy histories, and housing characteristic
14:03:49 5 information on a large population at high risk for
14:03:52 6 developing asthma." Do you see that?

14:03:53 7 A. Yes.

14:03:54 8 Q. Was that the large population of eight
14:03:58 9 hundred some infants that you analyzed in this study?

14:04:03 10 A. Yeah. I mean the reference there I -- I
14:04:06 11 think is towards the size of the study in comparison
14:04:11 12 to other studies of children's health and airborne
14:04:15 13 disease.

14:04:16 14 Q. Well you conclude, aside from the Augustine
14:04:18 15 2017 study, that the McGovern study is the only
14:04:22 16 observational data at hand regarding the use of the
14:04:26 17 Bair Hugger or a conductive warming device in deep
14:04:29 18 joint infections; correct?

14:04:29 19 A. Okay. Yeah.

14:04:30 20 Q. And that study had approximately 1400
14:04:33 21 patients; correct?

14:04:34 22 A. Yes.

14:04:34 23 Q. And in that study you're calling it
14:04:36 24 relatively small, but in this study you're calling a
14:04:38 25 population of 800 persons large.

14:04:41 1 A. Well we're -- we're talking about two
14:04:44 2 different things. It's small because what's -- in the
14:04:54 3 Hot Dog group there are only three or four infections.
14:04:59 4 Q. So the expected value -- the actual value.
14:05:03 5 A. So if we're looking at -- if you're --
14:05:04 6 If you -- what you want to do is design a --
14:05:06 7 an experiment that really addresses the question of
14:05:09 8 whether it reduces the rate of infection, 1400 is --
14:05:16 9 it's arguable about whether that is large enough a
14:05:20 10 study to do that.
14:05:21 11 Q. So it's unclear whether it's large or small.
14:05:23 12 A. Well I don't recall -- I --
14:05:25 13 I never saw a power analysis of this study.
14:05:29 14 And if you could show me one, I'd be glad to -- glad
14:05:33 15 to review it.
14:05:34 16 Q. So you never --
14:05:35 17 A. But -- but the -- the study was not designed
14:05:38 18 in the -- in the typical way that you would design a
14:05:41 19 study if you were seeking NIH funding or something
14:05:44 20 like that where you would be required to generate the
14:05:48 21 sample size.
14:05:49 22 Q. So you haven't --
14:05:50 23 A. That's what would be required, and that
14:05:53 24 would determine, you know, the -- the -- that would
14:05:55 25 determine -- be more relevant, it seems to me, in

14:05:58 1 terms of the size of the study and whether or not it
14:06:01 2 was big enough to address the particular hypothesis
14:06:06 3 that was being -- that was being proposed in the -- in
14:06:10 4 the proposal.

14:06:11 5 Q. So it's your view that it's a better metric
14:06:13 6 to use expected values than actual values, correct, to
14:06:17 7 determine whether you apply Fisher's instead of
14:06:19 8 chi-squared?

14:06:23 9 A. The -- the -- the typical rule of thumb
14:06:28 10 depends on the expected. In my own bias I've found
14:06:33 11 that sometimes the observed number can be relevant as
14:06:36 12 well.

14:06:37 13 Q. So based on your own bias, you relied on the
14:06:41 14 actual values reported in the study itself as opposed
14:06:43 15 to the expected values that most statisticians rely on
14:06:46 16 to determine whether to apply Fisher or not.

14:06:50 17 A. Yeah. That's probably less commonly used on
14:06:54 18 the observed values, but I prefer to do that because I
14:06:55 19 think in this case, actually, the expected values
14:06:58 20 are -- are greater, I -- I believe, than -- than --
14:07:05 21 than the nominal five, if that's the rule you're
14:07:08 22 using.

14:07:08 23 Q. The rule of thumb.

14:07:10 24 A. Yeah. If that's the rule you're using,
14:07:12 25 that --

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14:07:13 1 I haven't read this complete article. That
14:07:15 2 doesn't seem to be what the person that wrote this
14:07:19 3 article for Biological Statistics is using.

14:07:25 4 Q. You would agree, though, the general rule of
14:07:27 5 thumb with respect to implying -- employing Fisher's
14:07:31 6 exact test is whether the expected value is under
14:07:34 7 five; correct?

14:07:37 8 A. Yeah. I mean there -- there's a difference,
14:07:39 9 you understand, between recommending the choice, the
14:07:46 10 extra calculation that's involved with doing Fisher
14:07:49 11 exact as opposed to the easier calculation of doing
14:07:52 12 chi-square; they recommended doing it based on the
14:07:57 13 expected value being less than five.

14:07:58 14 Q. Uh-huh.

14:07:59 15 A. That's not to say that it's wrong to do the
14:08:04 16 Fisher's exact test otherwise.

14:08:06 17 Q. If you did an expected value calculation
14:08:09 18 based on the populations reported in the McGovern
14:08:12 19 study, it very well could exceed five for each arm of
14:08:17 20 the study; correct?

14:08:17 21 A. It could, yeah.

14:08:19 22 Q. But you --

14:08:20 23 A. We can do it. I --

14:08:21 24 Q. I can --

14:08:23 25 But you agree that that's possible.

14:08:25 1 A. Yes.

14:08:26 2 Q. And you didn't do it.

14:08:27 3 A. I think I did look at it. I think it is a
14:08:29 4 little bit greater, the expected value. But based
14:08:33 5 on -- as I say, I -- my --

14:08:36 6 What I have found very often, that the
14:08:39 7 difference can be larger than I like depending on the
14:08:45 8 observed number.

14:08:47 9 Q. And --

14:08:49 10 A. And in fact you see in my --

11 Q. Yeah.

14:08:50 12 A. -- report there's a difference in
14:08:52 13 p-values --

14:08:53 14 Q. And --

14:08:54 15 A. -- and that's why I did the Fisher. And I
14:08:57 16 find a difference.

14:08:58 17 Q. Yeah. You -- you use Fisher instead of
14:09:01 18 chi-squared; correct?

14:09:02 19 A. That's right.

14:09:04 20 Q. Even though the expected value is above
14:09:06 21 five.

14:09:06 22 A. That's right.

14:09:07 23 Q. Okay.

14:09:07 24 A. As I said, I mean it's not a --

14:09:09 25 It's a rule of thumb. It's not a --

14:09:12 1 Q. You didn't follow the rule of thumb.

14:09:13 2 A. I didn't follow the rule of thumb. I
14:09:16 3 followed my own rule of thumb.

14:09:18 4 Q. And that's contrary to generally accepted
14:09:20 5 methods; correct?

14:09:21 6 A. Well it's --

14:09:22 7 Q. It's a rule of thumb.

14:09:23 8 A. It's a rule of thumb that's sometimes
14:09:26 9 applied. I mean you apply --

14:09:28 10 Who is this, McDonald --

14:09:30 11 Q. Yeah.

12 A. -- in Exhibit 20?

14:09:30 13 Q. Handbook of Biostatistics.

14:09:32 14 A. Yeah. And McDonald is using a different
14:09:37 15 rule of thumb. He's not --

14:09:39 16 Q. Oh --

14:09:39 17 A. At least in that first paragraph. I haven't
14:09:41 18 read the whole thing.

14:09:41 19 Q. He uses the same rule. I'll give you the
14:09:44 20 other section of the handbook.

14:09:46 21 A. Yeah. Well it's all -- it's all right. I
14:09:49 22 mean I know there's -- there's a slight difference in
14:09:53 23 how the rule of thumb is sometimes -- sometimes
14:09:56 24 applied, but it's a rule of thumb that applies to the
14:09:59 25 approximation. What does the approximation -- when

14:10:02 1 did the approximation break down, and it particularly
14:10:06 2 breaks down if the expectation is small. My
14:10:09 3 contention is is that it breaks down also to some
14:10:12 4 extent when the observed values are small even though
14:10:15 5 the expected values may be large.

14:10:18 6 MR. SACCHET: We're going to mark another
14:10:19 7 exhibit here.

14:10:33 8 (Exhibit 22 was marked for
14:10:34 9 identification.)

14:10:34 10 A. The discreteness, for example, that we were
14:10:37 11 just talking about would also come into play to some
14:10:40 12 extent on chi-square, because I mean whenever you're
14:10:44 13 dealing with integers, the -- the chi-square
14:10:49 14 statistics that you -- that you get at the end is only
14:10:52 15 going to take discrete values, it's not going to take
14:10:56 16 a complete -- a continuum of values. So the
14:11:00 17 particular criticism that -- that comes into play with
14:11:05 18 Fisher's also, I would say, comes into effect to some
14:11:09 19 extent on chi-square.

14:11:11 20 Q. This --

14:11:12 21 If you turn to the last page of this
14:11:14 22 document, professor, is also part of McDonald's 2014
14:11:20 23 Handbook on Biological Statistics; correct?

14:11:23 24 A. Apparently.

14:11:23 25 Q. Last page of the document. Do you see that

14:11:26 1 citation in the third kind of --

14:11:29 2 A. Yeah, appears to be.

14:11:30 3 Q. Yeah. And if you turn to page four of the

14:11:33 4 document under "Similar tests" --

14:11:37 5 Do you see that heading?

14:11:38 6 A. Yes.

14:11:38 7 Q. In the third paragraph, the very first line

14:11:41 8 says, "The usual rule of thumb is that you should use

14:11:44 9 the exact test when the smallest expected value is

14:11:48 10 less than 5...;" correct?

14:11:48 11 A. Where did you see this?

14:12:03 12 Q. Are -- are you on page four? On the very

14:12:05 13 top of the document there's pages X through seven.

14:12:08 14 Are you on page four?

14:12:10 15 A. Yeah. Which paragraph were you on?

14:12:15 16 Q. Was I looking at the wrong document?

14:12:18 17 There's a heading called "Similar tests."

14:12:19 18 A. That's right.

14:12:20 19 Q. Okay. And then in the -- I guess it's the

14:12:23 20 fourth paragraph because the first line just a sole

14:12:26 21 line, the paragraph begins, "The usual rule of

14:12:29 22 thumb" --

14:12:30 23 A. Oh, okay.

14:12:31 24 Q. -- "is that you should use the exact test

14:12:32 25 when the smallest expected value is less than 5..."

14:12:35 1 A. That's right. Yeah, I -- I thought you were
14:12:37 2 referring to the third paragraph.

14:12:39 3 Okay. Yes.

14:12:40 4 Q. So that that corroborates the fact that in
14:12:44 5 this handbook the rule of thumb is that the expected
14:12:45 6 value should be less than five to apply Fisher's.

14:12:48 7 A. Yeah, which is what I -- which is what I
14:12:50 8 said, you know, --

14:12:51 9 Q. Okay.

14:12:52 10 A. -- a few minutes ago.

14:12:56 11 Q. Okay. As to the p-value that you calculated
14:13:04 12 using Fisher's instead of chi-squared, on the data
14:13:12 13 derived from Albrecht 10 and McGovern 16 the p-value,
14:13:18 14 as we stated, is 0.0507; correct?

14:13:22 15 A. That's the value I got, yes.

14:13:25 16 Q. And the difference between that p-value and
14:13:28 17 the p-value when you use chi-squared on the reanalyzed
14:13:32 18 data of 0.048 is a matter of a thousandth of a decimal
14:13:38 19 place; correct?

14:13:40 20 A. Well it's point -- it's twen --

14:13:52 21 It's a difference of .2 -- 027; right?

14:13:59 22 Q. I've got a difference of .0009.

14:14:06 23 A. I thought we were comparing --

14:14:09 24 Q. Let's see. The difference between .0507 --

14:14:14 25 A. And .048.

14:14:20 1 Q. .048. Yeah.

2 A. Well that's a difference --

14:14:22 3 Q. I don't think mine's right.

14:14:22 4 A. -- of .0027.

14:14:27 5 Q. 0027.

14:14:28 6 A. Yeah.

14:14:29 7 Q. And that is, in percentage value, .27

14:14:32 8 percent; correct?

14:14:33 9 A. Correct.

14:14:34 10 Q. And as a raw figure it's -- forgive my

14:14:40 11 mathematical ignorance -- two-thousandths of a decimal

14:14:45 12 point?

14:14:49 13 A. Two --

14:14:51 14 Well it rounds up to, I think, three. But

14:14:54 15 anyway, yeah.

14:14:55 16 Q. Okay. Three-thousandths of a decimal point?

14:14:59 17 A. Right.

14:15:00 18 Q. And that's the basis by which you say that

14:15:03 19 the McGovern data goes from non-significance to

14:15:07 20 significance -- or significance to non-significance;

14:15:10 21 correct?

14:15:10 22 A. No. I mean the definition of -- of

14:15:14 23 significance, is it above or below the line?

14:15:17 24 Q. That's the conven --

14:15:18 25 A. Critically thinking, that's the -- that's

14:15:22 1 the definition of it.

14:15:23 2 Q. It's a conventional line; correct?

14:15:25 3 A. It's the line that's often used. It's
14:15:28 4 obviously arbitrary, but it's the one that is very
14:15:30 5 often used.

14:15:31 6 Q. You agree that it's arbitrary.

14:15:34 7 A. Oh, yeah.

14:15:34 8 Q. And do you agree with The American
14:15:36 9 Statistical Association's recent statement that the
14:15:40 10 confidence levels of five percent and 10 percent are,
14:15:43 11 quote, "at best useful conventions?"

14:15:47 12 MR. GORDON: Object to the form of the
14:15:49 13 question.

14:15:52 14 A. I mean they're -- they're conventions that
14:15:55 15 are often used, yeah.

14:15:56 16 Q. Do you agree with the statement that they
14:15:58 17 are at best useful conventions?

14:16:00 18 MR. GORDON: Same objection.

14:16:03 19 A. That sounds -- I --

14:16:05 20 I think I would agree with that.

14:16:07 21 Q. Are you aware that certain peer-reviewed
14:16:11 22 journals have recently decided to ban the use of
14:16:13 23 p-values?

14:16:14 24 MR. GORDON: Object to the form of the
14:16:15 25 question, lack of foundation.

14:16:18 1 A. I'm aware that some journals some time
14:16:22 2 ago -- I'm not sure, I thought they had retracted on
14:16:25 3 that somewhat more recently, but there was a -- there
14:16:30 4 was a period of time where they went through -- some
14:16:35 5 journals went through that -- the thing about --
14:16:37 6 about -- about the p-values.

14:16:44 7 Q. Do you know Ron Wasserstein, who I think is
14:16:47 8 the president of the ASA?

14:16:49 9 A. I don't know him, --

14:16:50 10 Q. Okay.

14:16:51 11 A. -- no.

14:16:51 12 Q. Would you agree with his statement that the
14:16:58 13 p-value is not intended to be a substitute for
14:17:01 14 scientific reasoning?

14:17:02 15 MR. GORDON: Object to the form of the
14:17:04 16 question and lack of foundation.

14:17:09 17 A. You know, I'm -- I'm not sure what the whole
14:17:11 18 statement was that he is -- that he is talking about.
14:17:14 19 I mean certainly on the surface that --

14:17:18 20 It's not -- it's not the sole basis for
14:17:21 21 scientific reasoning, is that what you're saying? I
14:17:23 22 mean --

14:17:24 23 Q. His quote is the p-value is never intended
14:17:27 24 to be a substitute for scientific reasoning, end
14:17:30 25 quote.

14:17:30 1 A. Okay.

14:17:31 2 Q. Do you agree with that statement?

14:17:32 3 A. Yeah, uh-huh.

14:17:33 4 Q. And do you also agree with the statement
14:17:35 5 that p-values -- a p-value of less than .05 is not a
14:17:43 6 line that separates real results from false ones?

14:17:48 7 A. Well certainly, yeah.

14:17:50 8 Q. Okay. So if those --

14:17:54 9 Well I'll ask you one more question. Do you
14:17:57 10 agree that practices that reduce data analysis or
14:18:01 11 scientific inference to mechanical bright-line rules,
14:18:05 12 such as the p-value of being less than .05 for
14:18:09 13 justifying scientific claims or conclusions, can lead
14:18:12 14 to erroneous beliefs and poor decision-making?

14:18:16 15 A. Yes.

14:18:18 16 Q. One of your conclusions in this report is
14:18:21 17 that the McGovern data is invalid because the p-value
14:18:23 18 is .0507; correct?

14:18:26 19 A. Well I think that's a --

14:18:29 20 You're mixing -- you're mixing different --
14:18:33 21 different issues here. McGovern, as I understand the
14:18:39 22 way it's being used here, is to -- is not as a -- it's
14:18:53 23 used to try to say that there is strong scientific
14:18:57 24 evidence that infection rates for Bair Hugger are
14:19:02 25 higher than the Hot Dog warmer.

14:19:07 1 Q. My question is just about this p-value which
14:19:10 2 you use on page six of your report where you say, "The
14:19:14 3 reasons why McGovern et al conclusions are not valid
14:19:17 4 is because the p-value is close but not statistically
14:19:20 5 significant." That's one of your conclusions; is that
14:19:23 6 not correct?

14:19:24 7 A. Well the -- my con -- yes, my --
14:19:26 8 Well, what I'm saying is the evidence is not
14:19:28 9 strong. Whether you say the p-value is .0507 --

14:19:33 10 Q. Okay.

14:19:34 11 A. -- or .048, those are not wildly small
14:19:39 12 p-values to say that there is extremely strong
14:19:44 13 evidence here of an association.

14:19:45 14 Q. But you would agree that the fact that it's
14:19:47 15 just over statistical significance does not mean that
14:19:51 16 the results are invalid.

14:19:52 17 A. The conclusions --
14:19:53 18 My conclusions are not terribly different
14:19:56 19 from either one of those p-values.

14:19:58 20 Q. Okay. So whether --

21 A. They're -- they're --

14:19:59 22 Q. -- it's marginally significant or just over
14:20:02 23 statistical significance does not matter.

14:20:03 24 A. They're -- they're all -- both on the
14:20:06 25 border.

14:20:06 1 Q. Okay.

14:20:07 2 A. I mean what I'm doing, if -- and what I --

14:20:10 3 Part of what I'm commenting here and part of

14:20:13 4 what I would disagree with is a comparison with what

14:20:18 5 Samet is saying.

14:20:19 6 Q. Okay. We'll get to that.

14:20:20 7 A. Samet is saying that the evidence is very

14:20:23 8 strong.

14:20:23 9 Q. Okay.

14:20:23 10 A. Okay? And what I'm saying is that it's not

14:20:26 11 that strong, it's right on the cusp.

14:20:28 12 Q. Are you aware that under the law, the

14:20:31 13 Supreme Court of the United States of America has

14:20:33 14 stated that statistically significant p-values are not

14:20:37 15 necessary to determine causation?

14:20:40 16 MR. GORDON: Object to the form of the

14:20:42 17 question and lack of foundation.

14:20:44 18 A. I -- I'm not familiar with -- with what the

14:20:47 19 Supreme Court said or exactly what they were dealing

14:20:50 20 with.

14:20:50 21 Q. So your report does not account for the

14:20:53 22 legal standard that applies to determinations of

14:20:56 23 causation as a matter of law.

14:20:57 24 MR. GORDON: Object to the form of the

14:20:58 25 question, lack of foundation.

14:21:00 1 A. Is that --

14:21:00 2 Is the Supreme Court talking about a matter
14:21:02 3 of -- matter of law, or you were -- you were stating
14:21:05 4 it as -- as scientific -- as a scientific -- statement
14:21:14 5 of scientific fact?

14:21:15 6 Q. Quote, "A lack of statistically significant
14:21:18 7 data does not mean that a medical expert has no
14:21:20 8 reliable basis for inferring a causal link between a
14:21:23 9 product and an adverse event," end quote.

14:21:27 10 A. The lack of -- I -- I --

14:21:30 11 I don't know.

14:21:30 12 MR. GORDON: I'll object to the form of the
14:21:31 13 question.

14:21:31 14 A. Yeah. I don't really understand what --
14:21:34 15 what they're -- what they're getting at. I would have
14:21:37 16 to --

14:21:37 17 Q. Would it help to see the statement?

14:21:39 18 A. I'd have to review the statement. I mean
14:21:41 19 how --

14:21:43 20 What is it, a whole report?

14:21:45 21 Q. It's a case, and we don't have time for you
14:21:48 22 to read the whole case, but --

14:21:50 23 A. I mean that's --

14:21:51 24 I'd have to figure out what the case is
14:21:53 25 talking about. It -- it's --

14:21:55 1 I'm not a lawyer, obviously, and so I'm --

14:21:59 2 I'm not sure what distinctions that they're -- that

14:22:03 3 they're making. Their language is sometimes a little

14:22:05 4 different.

14:22:06 5 MR. SACCHET: Okay. Let's take a break.

14:22:08 6 THE REPORTER: Off the record, please.

14:31:05 7 (Recess taken.)

14:31:05 8 BY MR. SACCHET:

14:31:08 9 Q. Professor Holford, in your report you also

14:31:11 10 note that applying Fisher's exact test on the data

14:31:15 11 derived from Albrecht Exhibit 10 and McGovern Exhibit

14:31:18 12 16 yields a confidence interval of .97 to 10.82;

14:31:24 13 correct?

14:31:24 14 A. Yes.

14:31:25 15 Q. And essentially that .97 is just .03 away

14:31:33 16 from the null value of one; correct?

14:31:35 17 A. That's right.

14:31:35 18 Q. So it's subject to this same debate about

14:31:38 19 just over/just under.

14:31:41 20 A. It's just -- it's just under the critical

14:31:42 21 value.

22 Q. Yes.

14:31:43 23 A. I mean it corresponds --

14:31:44 24 It's a little less because the p-value is a

14:31:48 25 little high.

14:31:48 1 Q. And you conclude that one of the issues with
14:31:52 2 that confidence interval is it's essentially 10 points
14:31:54 3 and therefore there's -- there could be unreliability
14:31:58 4 to the data; correct?

14:32:00 5 A. Well the estimate of the -- of the odds
14:32:04 6 ratio is -- is not precise at all. I mean it's a
14:32:08 7 ten-fold difference, ten-fold range.

14:32:11 8 Q. So I was confused because when I read your
14:32:13 9 report and I saw your real analysis of the Jensen
14:32:16 10 data --

14:32:16 11 Which you did applying Albrecht Exhibit 10;
14:32:19 12 correct?

14:32:19 13 A. Yes.

14:32:20 14 Q. -- the confidence interval of your
14:32:22 15 calculation is 25 points wide.

14:32:27 16 A. I forget what the range was. It was pretty
14:32:30 17 wide.

14:32:34 18 Where was it?

14:32:34 19 Q. It's on page five.

14:32:35 20 A. Page five. So you're referring to the 1.37
14:32:44 21 to 25.49.

14:32:45 22 Q. Yeah.

14:32:46 23 A. Yeah. Yeah. It's not a very good estimate.

14:32:48 24 Q. It's double the size of the confidence
14:32:51 25 interval that you critique with respect to the

14:32:54 1 McGovern study; correct?

14:32:54 2 A. That's right. It's statistically
14:32:56 3 significant, but the -- but the -- but it's not a good
14:33:00 4 estimate of what the risk is.

14:33:02 5 Q. So it has double the variance as the
14:33:05 6 confidence interval in the McGovern study.

14:33:07 7 A. Well it's -- it seems to be double the --
14:33:11 8 the range, the -- the -- the length of the -- of the
14:33:14 9 confidence interval.

14:33:16 10 Q. But you rely on this calculation with
14:33:18 11 respect to arguing whether or not the
14:33:22 12 thromboprophylaxis that was used in the McGovern study
14:33:24 13 is in fact a confounding factor; correct?

14:33:27 14 A. Well I'm --

14:33:30 15 I was looking at the p-value. The p-value
14:33:33 16 that I get associated with that is .006 --

14:33:36 17 Q. Uh-huh.

14:33:37 18 A. -- 4, so it's quite a small p-value. The
14:33:42 19 estimate of what that effect is is quite imprecise
14:33:46 20 because of -- you know, because of the range that we
14:33:49 21 were just talking about.

14:33:50 22 Q. It's more imprecise than the McGovern
14:33:54 23 study's confidence interval that you critique.

14:33:57 24 A. Well it's more imprecise in --

14:34:00 25 In general what happens with the -- with

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14:34:04 1 the -- with the confidence interval is it kind of
14:34:10 2 depends on the logarithm, so it's more on the log
14:34:14 3 scale, so that's part of what happens. I mean this
14:34:17 4 odds ratio is 4.77, so it's quite a bit bigger than
14:34:21 5 the odds ratios we were finding associated with Bair
14:34:25 6 Hugger use. So that's -- that's of course just a
14:34:29 7 point estimate, and so we're talking about a higher
14:34:31 8 range, so the range is going to be -- going to tend to
14:34:36 9 be somewhat wider because -- because we're up there.
14:34:39 10 And of course the -- the total sample size, total
14:34:44 11 number of individuals involved is -- is quite a bit
14:34:48 12 smaller than -- than -- because it -- it's just
14:34:53 13 based --

14:34:54 14 It comes out to be a subset of the -- of the
14:34:59 15 Bair Hugger study because it's only the Bair Hugger
14:35:02 16 period, so it's reduced in that way, and then the
14:35:06 17 other thing is that it's not the entire period, it's
14:35:09 18 just part of it, so we -- you're splitting that data
14:35:12 19 set up. And so your total sample size has gone down,
14:35:15 20 and that increases the -- that decreases the sample
14:35:19 21 size and in general makes the estimates less precise.

14:35:24 22 Q. But there's no doubt that the confidence
14:35:26 23 interval in this Jensen reanalysis, which is in your
14:35:29 24 report on page five, is double the width of the
14:35:32 25 McGovern confidence interval; correct?

14:35:33 1 A. That seems to be what it is, yes.

14:35:36 2 Q. That is what it is.

14:35:37 3 A. Okay. Yeah.

14:35:42 4 Q. Your report also states that when applying
14:35:46 5 Albrecht Exhibit 10 and McGovern Exhibit 16, that the
14:35:49 6 p-value -- or that the odds ratio is 2.76 when using
14:35:53 7 Fisher's exact; correct?

14:35:57 8 A. Well that -- that -- yeah. And that --
14:35:59 9 that's not --

14:36:00 10 The -- the test, the Fisher's exact, has to
14:36:03 11 do with the p-value, not the -- not the estimate of
14:36:05 12 what the odds ratio is.

14:36:06 13 Q. So on page two of your report when you say
14:36:10 14 the odds ratio for this comparison is 2.76, where did
14:36:16 15 you get that from?

14:36:16 16 A. That's just a cross-product ratio for that
14:36:19 17 table.

14:36:20 18 Q. And is that -- okay.

14:36:22 19 So the 2.76 derives from Albrecht Exhibit 10
14:36:26 20 and McGovern Exhibit 16.

14:36:28 21 A. That's right. It's a tabulation of those
14:36:30 22 data. I mean it's --

14:36:32 23 Yeah.

14:36:32 24 Q. And it's only accurate insofar as those
14:36:35 25 exhibits are accurate; correct?

14:36:37 1 A. Well the accuracy depends on -- on the -- on
14:36:44 2 the --

14:36:44 3 Q. Cross product.

14:36:47 4 A. Well the point estimate is the cross
14:36:50 5 product. The -- the confidence interval depends on
14:36:54 6 this Fisher-like distribution. It's not --

14:36:59 7 It's an exact kind of calculation that --
14:37:03 8 that -- that's involved, but it's kind of a lengthy
14:37:07 9 calculation that roughly depends on the standard
14:37:10 10 error.

14:37:11 11 Q. So I might need to back up because I don't
14:37:14 12 know if I'm fully understanding what you're saying.
14:37:16 13 But the odds ratio reported in the McGovern study was
14:37:20 14 3.8; correct?

14:37:21 15 A. Yes.

14:37:21 16 Q. And then in your report on page two you say
14:37:24 17 the odds ratio for this comparison is 2.76, and
14:37:28 18 what --

14:37:28 19 A. That's in the tabulation I used, yes.

14:37:31 20 Q. -- what data are you using to derive that
14:37:33 21 odds ratio?

14:37:35 22 A. The --

14:37:36 23 MR. GORDON: Arithmetically, or the
14:37:39 24 underlying data?

14:37:40 25 MR. SACCHET: Arithmetically.

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14:37:42 1 A. Well it's the -- it's the -- two point --

14:37:47 2 Where is that? Oh, here we are. Okay.

14:37:52 3 Yeah. That's based on this -- this table that is the

14:37:59 4 four out of 372 and 31 out of 1065.

14:38:03 5 Q. And where did you get that data?

14:38:06 6 A. That's from -- from --

14:38:07 7 Was it Albrecht 10?

14:38:09 8 Q. Okay. You would agree that that odds ratio

14:38:13 9 is still above 2.0; correct?

14:38:16 10 A. Yes.

14:38:17 11 Q. Would you agree that an odds ratio of 2.0 is

14:38:26 12 often referred to as a doubling of the risk?

14:38:27 13 A. It -- it is, yeah.

14:38:28 14 Q. And -- and that means you're 50 percent more

14:38:32 15 likely to experience the outcome after exposure to the

14:38:39 16 variable than the count as actual?

14:38:42 17 MR. GORDON: Object to the form of the

14:38:43 18 question.

14:38:50 19 A. Well if -- what it would imply, if -- if --

14:38:55 20 if the odds ratio was -- if the --

14:39:00 21 The odds ratio is actually a ratio of odds.

14:39:05 22 The statement that you made as -- is re -- is

14:39:08 23 related -- you state it as a ratio of -- of risks,

14:39:14 24 which would typically mean a ratio of the -- of the

14:39:20 25 incidence rates.

14:39:23 1 Q. Okay.

14:39:24 2 A. So when the incidence rates are small, those
14:39:28 3 two are very similar, okay, and so they're roughly
14:39:34 4 used in that way. So an odds ratio of two, it's --
14:39:40 5 strictly speaking it's twice the odds of getting an
14:39:43 6 infection, although it's going to be very close as --
14:39:49 7 to -- to twice the incidence.

14:39:51 8 Q. Okay.

14:39:52 9 A. So if -- well if -- if you're saying that
14:40:02 10 the -- the Hot Dog is the norm and the odds ratio is
14:40:06 11 two, that would say that the Bair Hugger has twice the
14:40:10 12 risk.

14:40:10 13 Q. Okay.

14:40:11 14 A. That's how -- how you would roughly
14:40:13 15 interpret that statement.

14:40:14 16 Q. Okay.

14:40:15 17 A. Depending on whether or not -- whether that
14:40:17 18 statement is correct we might disagree on, but --

14:40:20 19 Q. So if the incidence of disease in an exposed
14:40:24 20 group is more than twice the incidence in the
14:40:28 21 unexposed group, the probability that exposure to the
14:40:29 22 agent caused a similarly situated individual is also
14:40:33 23 greater than 50 percent; correct?

14:40:38 24 A. If -- if that estimate is -- is accurate,
14:40:47 25 that's roughly what it would -- what it would be --

14:40:50 1 what it -- what it would mean.

14:40:51 2 Q. Thank you.

14:40:52 3 Okay. I'd like to talk a little bit about
14:41:02 4 the other section of your report which deals with the
14:41:06 5 time trend infection rates at Wansbeck, and I guess
14:41:12 6 really the -- the big header is "Infection rate
14:41:14 7 comparison among hospitals" starting on page three, at
14:41:17 8 the bottom of page three, and then continuing into
14:41:20 9 four and five.

14:41:25 10 So to be clear, in your report you note that
14:41:32 11 there is a .6 percent infection rate among NHS trust
14:41:38 12 in 2010 to 2015; correct?

14:41:42 13 A. Yes.

14:41:47 14 Q. And when you cite a 2.9 percent infection
14:41:55 15 rate at the top of page four, that is based also on
14:42:05 16 the Albrecht Exhibit 10 and McGovern Exhibit 16 data;
14:42:09 17 correct?

14:42:09 18 A. That's right.

14:42:11 19 Q. And to be clear, that infection rate as it
14:42:15 20 relates to Bair Hugger patients was during the 2008
14:42:19 21 and 2009 time period; correct?

14:42:22 22 A. That's correct.

14:42:25 23 Q. So you are comparing an infection rate of
14:42:29 24 Bair Hugger patients in 2008 and 2009 to an infection
14:42:32 25 rate from 2010 to 2015.

14:42:35 1 A. That's right.

14:42:36 2 Q. They are two different time periods;

14:42:40 3 correct?

14:42:40 4 A. That's correct.

14:42:41 5 Q. That's an apples-to-orange comparison; isn't

14:42:47 6 it?

14:42:47 7 MR. GORDON: Object to the form of the

14:42:48 8 question.

14:42:51 9 Q. Let me put it this way: It's not externally

14:42:54 10 generalizable.

14:42:56 11 A. It's not --

14:42:58 12 What do you mean?

14:42:59 13 Q. It's not externally valid. I mean if -- if

14:43:02 14 you're looking at a date range of 2010 to 2015, you

14:43:06 15 don't know for sure whether that --

16 A. Yeah.

14:43:07 17 Q. -- infection rate should apply to prior

14:43:09 18 years; do you?

14:43:09 19 A. Well if -- if things are reasonably --

14:43:12 20 I mean the -- the assumption there is that

14:43:15 21 there's not a huge temporal trend going on in

14:43:18 22 infection rates in the U.K., and so my -- my

14:43:24 23 assumption is -- I -- I didn't have --

14:43:27 24 Ideally, I would have had the data for the

14:43:30 25 same years. I didn't.

14:43:31 1 Q. Okay.

14:43:32 2 A. And so I used the best data that I could get
14:43:36 3 ahold of to -- to see what the experience was at other
14:43:41 4 hospitals using Bair Hugger at this time to get a
14:43:46 5 comparison of how Wansbeck fit -- fit in with the --
14:43:52 6 with the experience at other hospitals.

14:43:54 7 Q. Did you try to get data from 2008 to 2009?

14:43:58 8 A. I didn't have -- I didn't have a -- didn't
14:44:01 9 come across a good way of doing that.

14:44:02 10 Q. Okay. But you recognize that it's two
14:44:05 11 different time periods.

14:44:06 12 A. Yes, I do. Uh-huh.

14:44:08 13 Q. Are you aware of infection rates in the
14:44:13 14 United States as opposed to infection rates reported
14:44:15 15 by the NHS in the U.K.?

14:44:18 16 A. No. I don't know what the rates are in the
14:44:21 17 U.S.

14:44:21 18 Q. So you do not know whether the rates of
14:44:25 19 infection as reported in the McGovern study are
14:44:28 20 comparable to rates in the United States.

14:44:30 21 A. I don't have a direct es -- estimate of
14:44:33 22 rates in the United States. My assumption is that
14:44:36 23 they're not too different, but --

14:44:37 24 Q. But --

14:44:38 25 A. -- I don't know. I don't have the data.

14:44:40 1 Q. -- with respect to your analysis as to
14:44:41 2 whether the time trend data of infections as reported
14:44:43 3 in McGovern is out of control, as you say, that is
14:44:47 4 only as compared to hospitals in the U.K. from 2010 to
14:44:53 5 2015.

14:44:56 6 A. In terms of the magnitude of the effect,
14:44:58 7 that's -- that was one of the pieces of evidence that
14:45:00 8 I was -- that I was looking at.

14:45:02 9 Q. But it's only specific to hospitals in the
14:45:04 10 U.K.

14:45:05 11 A. That's right. I was using data in the U.K.

14:45:07 12 Q. Okay.

14:45:28 13 (Exhibit 23 was marked for
14:45:29 14 identification.)

14:45:29 15 BY MR. SACCHET:

14:45:35 16 Q. Professor Holford, is this a graph bearing
14:45:37 17 the title "Joint infection rate in BH unit sales by
14:45:43 18 year?"

14:45:45 19 A. Yes.

14:45:46 20 Q. Okay. And do you know what ICD codes are?

14:45:56 21 A. Yes. Those are disease codes for -- for
14:46:01 22 different diseases, yes, that are standardized.

14:46:07 23 Q. They relate to disease in the United States.

14:46:11 24 A. Are they only -- I don't -- I'm not sure
14:46:13 25 what -- what they use --

14:46:15 1 I don't know what they use in the U.K. This
14:46:17 2 is U.S. data, is it?
14:46:18 3 Q. I'll represent to you that it is.
14:46:20 4 A. Okay.
14:46:21 5 Q. And there are three colored lines; correct?
14:46:23 6 A. That's correct.
14:46:24 7 Q. And to be clear, the title is "Joint
14:46:27 8 infection rate...;" correct?
14:46:28 9 A. "Joint" --
14:46:30 10 Yes.
14:46:31 11 Q. Of the graph.
14:46:32 12 A. "Joint infection rate..."
14:46:33 13 Q. Not like surgical-site infection or other
14:46:35 14 type of infection, this is specific to joint
14:46:37 15 infection; correct?
14:46:39 16 A. That's right.
14:46:39 17 Q. Okay. And the two orange-colored lines
14:46:44 18 relate to infection rates; correct?
14:46:47 19 MR. GORDON: Objection, lack of foundation.
14:46:49 20 A. I don't know. I --
14:46:49 21 Q. Do you see the legend?
14:46:51 22 A. Oh, I see.
14:46:52 23 Q. Do you see the legend at the bottom?
14:46:55 24 A. Yeah. Okay.
14:46:56 25 Q. And then the Y axis on the right side of the

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14:46:59 1 graph is titled "Joint Infection Rates" and then it
14:47:03 2 lists an ICD code; correct?
14:47:06 3 A. Right.
14:47:06 4 Q. Or codes. Correct?
14:47:07 5 A. Right.
14:47:08 6 Q. And those percentages range from zero to
14:47:10 7 six, at least as depicted on the graph, correct, on
14:47:13 8 the Y axis on the right-hand side?
14:47:16 9 A. That's right.
14:47:16 10 Q. Okay. And whichever --
14:47:19 11 Well let's look at 2008, and that's when the
14:47:23 12 Bair Hugger study period started; correct?
14:47:28 13 A. 2008. Okay.
14:47:31 14 Q. And the lower orange line, the dot there is
14:47:36 15 approximately four percent; correct?
14:47:41 16 A. Four percent.
14:47:44 17 MR. GORDON: Again, lack of foundation.
14:47:45 18 A. Seems to be.
14:47:46 19 Q. And the dot above that is between four and
14:47:50 20 five.
14:47:55 21 A. Somewhere --
14:47:57 22 Something, yeah.
14:47:57 23 Q. Okay.
14:47:57 24 A. What are the two lines? I don't
14:47:59 25 understand, --

14:47:59 1 Q. So there's an infection rate --

14:48:03 2 A. -- it's hard to read.

14:48:05 3 Q. And I'm not going to focus on which line,

14:48:08 4 you know, we need to focus on, I just want to

14:48:11 5 establish that both lines depict infection rates --

14:48:15 6 A. Okay.

14:48:16 7 Q. -- equal to or greater than four but less

14:48:19 8 than five in 2008; correct?

14:48:20 9 A. Yeah.

14:48:21 10 Q. Okay. And then in 2010 the dots appear to

14:48:26 11 be the same, somewhere between four and five; correct?

14:48:29 12 A. Right.

14:48:31 13 Q. And in fact in 2011 they went up to

14:48:33 14 approximately 4.5 and five; correct?

14:48:37 15 A. Appears to, yeah.

14:48:38 16 Q. Yeah. So if we can find the graph to the

14:48:43 17 Bair Hugger study period, which is 2008 to 2010, based

14:48:47 18 on this graph the infection rate is four percent or

14:48:51 19 perhaps 4.5 percent; correct?

14:48:55 20 A. Infection --

14:48:55 21 MR. GORDON: Objection, lack of foundation.

14:49:02 22 A. So I -- I mean what -- what do these -- what

14:49:08 23 do the ICD codes --

14:49:11 24 Q. ICD codes --

14:49:12 25 I can't testify, but ICD codes, as you

14:49:15 1 stated earlier, --

14:49:16 2 A. Yeah.

14:49:17 3 Q. -- relate to particular outcomes of disease.

14:49:19 4 A. No. But what is ICD-9 -- 996.66?

14:49:28 5 Q. I don't know the answer to that question,

14:49:30 6 but I can tell you that 3M's corporate representative,

14:49:33 7 Mr. Van Duren, testified that this graph depicts the

14:49:41 8 rate of Bair Hugger segment penetration with the rate

14:49:44 9 of joint infections.

14:49:51 10 A. Okay. So these are some sort of --

14:50:00 11 I'm having a hard time understanding what

14:50:02 12 you're trying to show here --

14:50:04 13 Q. I'm -- I'm --

14:50:04 14 A. -- because, I mean, we've got two

14:50:05 15 different -- two different lines of the infection

14:50:07 16 rates --

14:50:07 17 Q. So my question is --

14:50:08 18 A. -- and when -- when I --

14:50:10 19 I don't know what these two different lines

14:50:12 20 are.

14:50:12 21 Q. Okay. My question is simple.

14:50:13 22 A. Okay.

14:50:14 23 Q. Whichever line you choose, the infection

14:50:17 24 rate, according to this graph, in 2008 and 2010 was

14:50:20 25 4.0 or 4.5; --

14:50:23 1 A. Okay.

14:50:24 2 Q. -- is that correct?

14:50:25 3 MR. GORDON: Objection, lack of foundation,
14:50:26 4 assumes facts not in evidence, incomplete
14:50:30 5 hypothetical.

14:50:30 6 Q. According to this graph.

14:50:32 7 A. Those numbers that are shown, I don't -- and
14:50:35 8 as I say, I don't know what they are, you haven't told
14:50:37 9 me what they are, there's not a legend here that
14:50:39 10 exactly indicates what they are --

14:50:41 11 Q. The graph is called "Joint infection
14:50:42 12 rate...;" right?

14:50:43 13 A. That's what it -- that's what it's called.

14:50:45 14 Q. Okay.

14:50:45 15 A. But I mean if you look up the ICD code,
14:50:49 16 they're very specific on what -- what -- what they
14:50:52 17 mean. They're -- they're pretty speci -- specific,
14:50:56 18 and I just -- I don't know how those values -- how
14:51:03 19 those codes compare with --

14:51:11 20 I -- I mean I don't know where you're going
14:51:12 21 with this, if you want to compare these values to the
14:51:16 22 experience in -- in the U.K. or what -- what exactly
14:51:20 23 you're -- you're looking at.

14:51:21 24 Q. I'll -- I'll just cut to it. Based on this
14:51:24 25 graph -- and I'll make the assumption that these I --

14:51:27 1 ICD codes relate to joint infection as the graph is
14:51:30 2 entitled, --

14:51:31 3 A. Okay.

14:51:31 4 Q. -- the infection rate of four percent is
14:51:34 5 higher than the infection rate reported by McGovern et
14:51:37 6 al.

14:51:38 7 MR. GORDON: Object to the form of the
14:51:39 8 question, lack of foundation, assumes facts not in
14:51:43 9 evidence, incomplete hypothetical.

14:51:46 10 A. Well I mean what I don't understand about
14:51:50 11 your question is that you -- there's not a -- there's
14:51:56 12 no evidence of how this definition of joint infection
14:52:01 13 compares to what McGovern was looking at. What's the
14:52:08 14 denominator? What are -- what are -- exactly are --

14:52:11 15 I mean are these specific knee and hip
14:52:15 16 surgeries? I don't -- I don't know.

14:52:17 17 Q. Well just is --

14:52:18 18 A. It doesn't say.

14:52:19 19 Q. Okay. Assuming that it involves a different
14:52:22 20 category of infections, just for the sake of argument,
14:52:26 21 that's also a different group than looking at patients
14:52:30 22 from 2010 to 2010, isn't it, when the McGovern study
14:52:36 23 was about Bair Hugger patients from 2008 to 2009,
14:52:40 24 2010?

14:52:41 25 A. Well, but I think -- I mean it does say --

14:52:47 1 If you look at this graph, I mean those
14:52:49 2 orange lines are not changing very much between 1996
14:52:53 3 and 2012. Okay? They're pretty flat. And so my
14:53:00 4 comparison of -- of these two periods for the U.K.,
14:53:06 5 one of which was, what, --
14:53:10 6 Q. Two thousand --
14:53:12 7 A. -- two thousand --
14:53:15 8 Let's see. Bair Hugger is '8 to '9 and the
14:53:19 9 plot in this case, Fig. 1, has to do with '10 to '15.
14:53:28 10 Okay. So based on this, it doesn't seem to be -- look
14:53:36 11 to -- to my eyes to be a whole lot different
14:53:38 12 between -- before 2010 and between '10 and '15.
14:53:42 13 Q. Okay.
14:53:43 14 A. Would you agree?
14:53:45 15 Q. You assume, in calculating the deep joint
14:53:48 16 infection rate in the NHS, that there was complete
14:53:51 17 reporting practices among hospitals; correct?
14:53:54 18 A. Yeah, that's my assumption. Yeah.
14:53:56 19 Q. And if there were not complete reporting
14:53:58 20 practices, those averages would be subject, again, to
14:54:01 21 a data artifact; correct?
14:54:03 22 A. Yes.
14:54:04 23 Q. You said that you reviewed Dr. Reed's
14:54:07 24 testimony; correct?
14:54:07 25 A. Yes.

14:54:09 1 Q. And did you see where Dr. Reed said that
14:54:13 2 "Not every trust puts in the data as we have
14:54:16 3 established and the infection rates that they quote
14:54:18 4 were very low. And in fact government advisors on
14:54:22 5 infection have publicly written to say that their
14:54:25 6 quotes -- they quote very low infection rates,
14:54:27 7 unrealistically low, because the surveillance system
14:54:29 8 is poor in many trusts."

14:54:32 9 A. Okay. I mean it -- it may well be.

14:54:34 10 Q. So if it may well be, the .6 percent rate
14:54:40 11 that you report in your study may also well be subject
14:54:43 12 to data artifact.

14:54:46 13 A. The accuracy of -- of -- of that value
14:54:51 14 depends on the accuracy of the data that were reported
14:54:53 15 in the file that I looked at.

14:54:55 16 Q. And in your report you relied on Mr.
14:54:58 17 Reed's -- Dr. Reed's testimony regarding other subject
14:55:00 18 matter; correct?

14:55:01 19 MR. GORDON: Object to the form of the
14:55:02 20 question.

14:55:05 21 A. Yes, some of the other subject matter. I
14:55:07 22 mean I --

14:55:08 23 Q. You have no reason to doubt Mr. Reed's
14:55:11 24 testimony regarding the --

14:55:15 25 A. I --

14:55:16 1 Q. -- incomplete --

14:55:16 2 A. Yeah. I really don't --

14:55:17 3 I mean I have -- I have no reason to

14:55:23 4 question pro or con the -- the quality of the -- of

14:55:29 5 the U.K. data, the -- the NHS data.

14:55:33 6 Q. Do you rely on Dr. Reed's testimony only

14:55:35 7 when it supports your conclusions?

14:55:39 8 A. No. It's just -- I -- I'm -- I mean I'm

14:55:43 9 not --

14:55:47 10 Dr. Reed is expressing his view on -- on

14:55:50 11 the -- on those -- those NHS data. I have no basis to

14:55:58 12 know one way or the other how good those data are.

14:56:01 13 Q. So you have no basis to know one way or

14:56:03 14 the --

14:56:03 15 A. So I'm using their -- their data to get an

14:56:07 16 idea of what the -- what the rates -- what the rates

14:56:10 17 were, and those are the values that they reported.

14:56:12 18 Q. Did you investigate whether there is

14:56:14 19 complete reporting among hospitals in the NHS?

14:56:17 20 A. No.

14:56:18 21 Q. You simply assumed that there was complete

14:56:20 22 reporting.

14:56:21 23 A. I assume -- I assumed that the data --

14:56:24 24 I mean the data are what they are.

14:56:26 25 Q. You also assumed that hospitals that use the

14:56:29 1 Bair Hugger do not use other warming devices; correct?

14:56:32 2 A. That was --

14:56:34 3 I mean the assumption was that the primary
14:56:36 4 warmers that they were using in these hospitals was in
14:56:39 5 fact the Bair Hugger.

14:56:40 6 Q. In your report you state that 3M provided
14:56:42 7 you with documents that delineated whether or not a
14:56:46 8 hospital uses the Bair Hugger; correct?

14:56:49 9 A. I was provided with hospitals that were
14:56:52 10 using Bair Hugger and that's what I used. I don't --
14:56:56 11 didn't go into the detail of the -- of what was used
14:57:00 12 in these hospitals.

14:57:01 13 Q. So you didn't know based on those documents
14:57:05 14 because they didn't specify whether or not those
14:57:08 15 hospitals also used other devices.

14:57:10 16 A. The documents did not specify. The
14:57:13 17 documents --

14:57:14 18 The indication that I had was that they
14:57:17 19 used -- were using Bair Hugger.

14:57:19 20 Q. Are you aware that some hospitals in the NHS
14:57:22 21 used both Bair Huggers and conductive warmers?

14:57:26 22 MR. GORDON: Object to the form of the
14:57:27 23 question, lack of foundation, assumes facts not in
14:57:29 24 evidence.

14:57:31 25 A. I have not seen any data that -- that breaks

14:57:38 1 down the specific devices that they use and if they
14:57:44 2 use alternative devices.

14:57:45 3 Q. You said you reviewed Dr. Reed's testimony;
14:57:46 4 correct?

14:57:46 5 A. Yes.

14:57:47 6 Q. You didn't see in Dr. Reed's deposition
14:57:49 7 where he made clear that there are hospitals that use
14:57:51 8 both the Bair Hugger and conductive warming devices?

14:57:54 9 MR. GORDON: Object to the form of the
14:57:55 10 question, lack of foundation, assumes facts not in
14:57:57 11 evidence.

14:58:01 12 A. I don't know what he was referring to. I
14:58:05 13 don't know if he was looking at the same data set that
14:58:07 14 I was looking at.

14:58:08 15 Q. Okay. Did you investi --

14:58:09 16 A. So I don't know.

14:58:11 17 Q. Did you investigate to see whether or not
14:58:13 18 hospitals do use both devices beyond the documents
14:58:17 19 that 3M provided you?

14:58:18 20 A. I -- I didn't get any further information.
14:58:23 21 I mean it wouldn't surprise me that -- that some
14:58:30 22 hospitals -- I mean I don't --

14:58:33 23 I don't know if this is exhaustive of all of
14:58:36 24 the hospitals or just those that -- that -- that were
14:58:42 25 indicated as having used Bair Hugger devices.

14:58:44 1 Q. Did you ask 3M for more information as to
14:58:47 2 whether the data that they provided, which showed that
14:58:50 3 some hospitals used the Bair Huggers, may also use
14:58:53 4 other devices?

14:58:54 5 A. I didn't -- was not provided with any data
14:58:56 6 that indicated whether other devices were used by
14:59:00 7 any --

14:59:01 8 Q. Did you ask them whether or not --

14:59:04 9 A. Well my understanding was when it was given,
14:59:06 10 that those were using the Bair Hugger.

14:59:08 11 Q. And you also just testified that it may very
14:59:10 12 well be that they used other devices as well; correct?

14:59:13 13 A. Well I don't --

14:59:15 14 I didn't compare this to the list of all
14:59:17 15 hospitals in the U.K.

14:59:19 16 Q. Understood. But --

14:59:21 17 A. So there may be hospitals outside of this
14:59:23 18 data set, and there is an issue -- issue there that I
14:59:30 19 cannot -- you know, cannot speak to.

14:59:32 20 Q. But you recognize that other hospitals may
14:59:35 21 use --

22 A. It's possible.

14:59:37 23 Q. -- devices in addition to the Bair Hugger.

14:59:38 24 A. Sure. Yes.

14:59:39 25 Q. And if that is true, the statistic of an

14:59:42 1 infection rate of .6 from 2010 to 2015 may or may not
14:59:48 2 be attributable just to the Bair Hugger.

14:59:52 3 A. It depends on the act -- the degree to
14:59:56 4 which, which is -- is true, that they only used one
15:00:00 5 device and not the other.

15:00:02 6 Q. And you don't know that degree of accuracy.

15:00:04 7 A. I don't know the degree of accuracy. That
15:00:06 8 was not part of the data that I was provided as -- as
15:00:11 9 to measure.

15:00:13 10 Q. And you didn't ask for that data.

15:00:15 11 A. No.

15:00:30 12 Q. To the extent you argue that the infection
15:00:36 13 rate from 2010 to 2015 was .6 percent, are you aware
15:00:49 14 that there was a significant decrease in deep joint
15:00:55 15 infections in the NHS from 2013 to 2015?

15:01:04 16 A. I didn't have data specifically relating to
15:01:11 17 these.

15:01:11 18 Q. So you did not review the Public Health of
15:01:19 19 England's report entitled "Surveillance of Surgical
15:01:24 20 Site Infections in NHS Hospitals in England?"

15:01:26 21 A. No.

15:01:27 22 Q. Okay. So you're not aware that, according
15:01:36 23 to that document, there was a significant decrease in
15:01:39 24 the years of 2013 to '14 and 2014 to '15 and 2014 to
15:01:44 25 fif -- '15 -- I said that twice -- but from 2013 to

15:01:47 1 2015.

15:01:52 2 A. Yeah. I -- I mean maybe it was, or these --

15:01:55 3 That decrease changing the accuracy would go

15:01:59 4 to the reporting, as you said, that Dr. Reed reported

15:02:02 5 that it's notoriously inaccurately reported, so maybe,

15:02:07 6 yeah. I don't know what the magnitude of the

15:02:09 7 difference is. I -- I --

15:02:11 8 To answer your question specifically, I did

15:02:14 9 not review that document.

15:02:15 10 Q. Okay. To the extent that you argue that the

15:02:23 11 infection rate was .6 percent from 2010 to 2015, what

15:02:33 12 is your basis for determining that it is related to

15:02:36 13 the Bair Hugger as opposed to the other SSI

15:02:40 14 intervention practices that were incorporated in these

15:02:44 15 hospitals during that time?

15:02:45 16 MR. GORDON: Objection, object to the form,

15:02:48 17 and also misconstrues his testimony.

15:02:53 18 A. You know, I -- it's -- I mean I --

15:02:58 19 It's just using the values that they're --

15:03:00 20 they're using. The data that we had -- that I had

15:03:02 21 was -- did not provide information other than, as --

15:03:10 22 as I've said, that these were hospitals using Bair

15:03:14 23 Hugger and this was their infection rate. I don't

15:03:16 24 have information on -- on what other SSI methods they

15:03:23 25 might happen to have been using.

15:03:25 1 Q. Okay. You also argue that there is no
15:03:29 2 reason provided for why the McGovern authors started
15:03:33 3 the study period on July 1st, 2008; correct?

15:03:35 4 A. Yes.

15:03:36 5 Q. And you go on to argue that had the authors
15:03:39 6 began the study just one month earlier, the data would
15:03:43 7 show a change from significance to non-significance;
15:03:46 8 correct?

15:03:46 9 A. Using the chi-square test, yes.

15:03:50 10 Q. And again you assume, based on that
15:03:54 11 calculation as provided in the figures attached to
15:03:56 12 your report, that you had complete information with
15:04:00 13 respect to infection data prior to July 1st, 2008;
15:04:05 14 correct?

15:04:05 15 A. That's based on the Albright 10 -- Exhibit
15:04:10 16 10 data, yeah.

15:04:11 17 Q. And we've discussed that document.

15:04:12 18 A. Yes, uh-huh.

15:04:13 19 Q. And are you aware that Mr. Reed -- Dr. Reed
15:04:20 20 has testified that there was not full surveillance at
15:04:24 21 Wansbeck Hospital prior to July 1st, 2008?

15:04:29 22 A. Yes. I'm aware that he said that, yeah.

15:04:33 23 Q. Are you aware that he said that if one were
15:04:35 24 to look at data prior to the study period, there would
15:04:38 25 be, quote, big gaps in the period, end quote?

15:04:43 1 A. That's -- that's -- that's what he reported.

15:04:47 2 Q. Are you aware that Dr. Reed also testified
15:04:50 3 that to rely on data prior to July 1st, 2008 would be,
15:04:55 4 quote, very unreliable, end quote?

15:04:58 5 A. That's what he reported.

15:05:01 6 I mean related to this, I mean there's a --
15:05:04 7 there was a review of -- of the procedures that they
15:05:08 8 were using that's referred to in one of the other
15:05:11 9 papers --

15:05:12 10 What is the author? Starts with a G.
15:05:17 11 Gissell?

15:05:18 12 Q. Gillson.

15:05:19 13 A. Gillson. Thank you.

15:05:21 14 -- that this was all not reviewed until
15:05:24 15 December, so I'm not sure where -- what Reed is
15:05:30 16 referring to.

15:05:33 17 Q. So you don't believe Dr. Reed's testimony
15:05:36 18 that full surveillance began on Septem -- on July 1st,
15:05:40 19 2008.

15:05:41 20 A. Well he's -- he's depending on his
15:05:43 21 recollection, --

15:05:43 22 Q. Okay.

15:05:44 23 A. -- I assume, in his deposition.

15:05:45 24 Q. Uh-huh.

15:05:46 25 A. And I mean that's what he's -- what -- what

15:05:50 1 he said in his -- in his deposition; however, that
15:05:55 2 seems to not correspond in a peer-reviewed paper what
15:05:59 3 was said about when this was all reviewed.

15:06:02 4 Q. So is your statement that in the Gillson
15:06:04 5 article the authors there represented that the full
15:06:09 6 surveillance began in December of 2008?

15:06:11 7 A. It was reviewed in December.

15:06:13 8 Q. Reviewed in December. But you have no
15:06:15 9 knowledge --

10 A. I don't --

15:06:17 11 Q. -- as to whether --

15:06:17 12 A. It doesn't say when it was implemented, --

15:06:19 13 Q. Okay.

15:06:20 14 A. -- but that would imply, if it was not
15:06:22 15 reviewed until December, that it would have been not
15:06:25 16 implemented until maybe January. Right? I mean if
15:06:30 17 it's not --

15:06:32 18 Q. January '09?

15:06:33 19 A. '09. Yeah.

15:06:34 20 Q. Okay. So if full surveillance wasn't
15:06:38 21 implemented until January '09, --

15:06:40 22 A. Yes.

15:06:40 23 Q. -- you're relying on data from July -- prior
15:06:45 24 to July 2008.

15:06:47 25 A. These were the data that were -- were

15:06:48 1 provided. These were the data that I had available to
15:06:50 2 me.

15:06:50 3 Q. But --

15:06:51 4 So I just want to be clear. Based on what
15:06:53 5 you just said, it's either possible that full
15:06:57 6 surveillance began on July 1st, 2008 or --

15:07:00 7 A. Yes.

15:07:01 8 Q. -- perhaps even January 1st, 2009, --

15:07:03 9 A. So what --

15:07:04 10 Yeah.

15:07:04 11 Q. -- but you nonetheless constructed your
15:07:08 12 model on data that was prior to that time; correct?

15:07:12 13 A. That's -- that's right.

15:07:13 14 Q. And that data --

15:07:14 15 A. And --

15:07:15 16 Q. -- may or may not be complete.

15:07:17 17 A. And --

15:07:17 18 Q. Answer the question, please.

15:07:20 19 A. Well according to Reed's testimony, if
15:07:23 20 Reed's correct, if -- if -- if this is correct, that
15:07:27 21 might be true.

15:07:29 22 Q. Okay.

15:07:29 23 A. The other thing that's true, then, if that's
15:07:33 24 what in fact took place, is that six months -- or
15:07:38 25 whatever it is -- six months or so of McGovern is not

15:07:44 1 reporting appropriately.

15:07:46 2 Q. So if this document from the NHS says that
15:07:50 3 since July 2008 hospitals are required to have sys --
15:07:54 4 systems in place to identify patients who are included
15:07:57 5 in the surveillance and later admitted to hospitals
15:07:59 6 with an SSI, would that clarify any doubt as to when
15:08:03 7 full surveillance began in the NHS?

15:08:07 8 MR. GORDON: Object to the form of the
15:08:08 9 question, lack of foundation.

15:08:09 10 A. Well there is --

15:08:13 11 I mean you're -- you're raising questions
15:08:15 12 about how accurate the data were recorded, but I mean
15:08:19 13 all of these change -- changes took place during the
15:08:22 14 McGovern study.

15:08:24 15 Q. If Mr. Reed's testimony is true -- if Dr.
15:08:30 16 Reed's testimony is true --

15:08:33 17 MR. SACCHET: I just said "mister,"
15:08:34 18 but I --

15:08:36 19 (Discussion off the stenographic record.)

15:08:49 20 Q. Okay. If Mr. Reed's testimony is that full
15:08:55 21 surveillance began on July 1st, 2008, that is the
15:08:59 22 start of the Bair Hugger period in the McGovern study;
15:09:02 23 correct?

15:09:02 24 A. That's --

15:09:03 25 According to his deposition, that -- that's

15:09:06 1 what it corresponds to, yes.

15:09:08 2 Q. And you have no evidence to doubt that, do
15:09:12 3 you, Professor Holford?

15:09:14 4 MR. GORDON: Object to the form of the
15:09:15 5 question.

15:09:18 6 A. I mean the evidence to doubt it is that
15:09:21 7 seems to be somewhat contradictory to what Gillson
15:09:26 8 says, but I mean I -- I'm not going to -- you know, I
15:09:31 9 don't -- I'm -- I'm --

15:09:32 10 I'll -- I'll take -- I'll take him at his
15:09:36 11 word.

15:09:37 12 Q. Okay. And taking him at his word, full
15:09:39 13 surveillance starts on July 1st, 2008.

15:09:46 14 A. That's what he said.

15:09:47 15 Q. Yes.

15:10:12 16 (Exhibit 24 was marked for
15:10:14 17 identification.)

15:10:14 18 BY MR. SACCHET:

15:10:16 19 Q. Professor Holford, is this the Gillson
15:10:18 20 article that you are referring to that was cited in
15:10:21 21 your report?

15:10:23 22 A. Is this it? I don't think it is.

15:11:22 23 Q. Okay. Let me --

15:11:25 24 A. I -- let's see.

15:11:26 25 MR. SACCHET: I may have marked the wrong

15:11:27 1 document, professor. Is it -- I just --

15:11:29 2 I'll shortcut this because I think I might

15:11:31 3 have. Is the first line of the document you're

15:11:33 4 looking at actually from Brister, not Gillson?

15:11:36 5 MR. GORDON: Yeah.

15:11:37 6 MR. SACCHET: I may have given you the wrong

15:11:38 7 one.

15:11:39 8 MR. GORDON: That's what you want to give

15:11:40 9 him.

15:11:40 10 MR. SACCHET: Okay.

15:11:43 11 THE WITNESS: Yeah. I think this is one of

15:11:44 12 the ones that --

15:11:46 13 MR. SACCHET: Yeah. That's my fault.

15:11:47 14 THE WITNESS: Yeah. It's strange, because

15:11:49 15 the author is not -- doesn't appear on it, which is

15:11:52 16 kind of a --

15:11:53 17 MR. SACCHET: The author is there on the

15:11:55 18 top, it's just --

15:11:55 19 It's my fault.

15:11:57 20 THE WITNESS: Okay. Yeah. It was hard to

15:11:59 21 find the author on this one, that's what -- yeah.

15:12:03 22 Anyway --

15:12:04 23 MR. GORDON: This is al --

15:12:05 24 This Exhibit 24 is on his list of

15:12:07 25 references, it's just --

15:12:08 1 MR. SACCHET: Yeah, it's the Brister
15:12:09 2 article.

15:12:10 3 THE WITNESS: Yeah, okay. Yeah. I didn't
15:12:20 4 think this was Gillson, that's all. See, Gillson
15:12:31 5 is -- where are we -- same journal, 2014, June '17.
15:13:08 6 Is that true? That was --

15:13:10 7 Oh, no. It was published in 21 -- 2011.
15:13:14 8 Yeah, that's Brister.

15:13:16 9 MR. SACCHET: Yeah.

15:13:17 10 THE WITNESS: Yeah.

15:13:46 11 (Exhibit 25 was marked for
15:13:49 12 identification.)

15:13:49 13 BY MR. SACCHET:

15:13:49 14 Q. Is this the Gillson article that you were
15:13:52 15 referring to?

15:13:53 16 A. Yes, it is.

15:13:54 17 Q. Okay.

15:13:54 18 A. Yes.

15:13:55 19 Q. Can you point me to any particular statement
15:13:58 20 in this article where there's information that
15:14:02 21 contradicts Mr. Reed's testimony?

15:14:06 22 A. Oh. There's a figure somewhere in there,
15:14:25 23 which is practically illegible in this copy --

15:14:49 24 Q. I don't want to spend tons of time on this,
15:14:52 25 professor, but --

15:14:54 1 A. I've got a --

15:14:58 2 Q. -- one thing that might be helpful is you
15:15:00 3 would agree, wouldn't you, that this particular
15:15:02 4 document relates to Northumbria Healthcare; correct?

15:15:06 5 A. That includes Wansbeck, yeah.

15:15:09 6 Q. But it's not specific to Wansbeck; correct?

15:15:11 7 A. That -- that's correct.

15:15:13 8 Q. So even if, for the sake of argument, this
15:15:14 9 document said something to the effect that there was a
15:15:17 10 different time in which full surveillance occurred,
15:15:20 11 that may or may not be specific to Wansbeck.

15:15:23 12 A. Well I assume it would include Wansbeck.
15:15:26 13 I -- I don't know how they operate, but -- yeah.

15:15:29 14 Q. It's possible that Wansbeck may have been
15:15:30 15 ahead of the curve with respect to what NHS did as a
15:15:34 16 trust; correct?

15:15:35 17 A. I -- I guess that's possible.

15:15:37 18 Q. Okay. So even if there's a date in this
15:15:40 19 document that's specific to NHS, it does not
15:15:42 20 contradict Mr. Reed's testimony.

15:15:45 21 A. Not necessarily.

15:15:45 22 MR. GORDON: Object to the form of the
15:15:46 23 question, --

15:15:47 24 A. Well --

15:15:47 25 MR. GORDON: -- assumes facts not in

15:15:48 1 evidence.

15:15:49 2 A. --it may or may not. I don't know.

15:15:51 3 Q. Well let's just do an example. If this
15:15:53 4 document said that the NHS implemented full-scale
15:15:56 5 surveillance of DJI in 2015 -- which it doesn't, but
15:16:02 6 for the sake of argument assume that to be true --

15:16:05 7 A. Yeah. Well it --

8 MR. GORDON: Wait, wait.

15:16:06 9 A. It's -- it's talking about --

15:16:07 10 MR. GORDON: Wait, wait. Is there --

15:16:09 11 I don't think he was done with his question.

15:16:11 12 MR. SACCHET: I'm not. Thank you.

15:16:13 13 Q. -- even if there was such a suggestion in
15:16:15 14 this paper, that does not preclude the possibility
15:16:19 15 that Wansbeck started full-scale surveillance for
15:16:22 16 itself on July 1st, 2008.

15:16:24 17 MR. GORDON: Object to the form of the
15:16:25 18 question, also assumes facts not in evidence.

15:16:28 19 A. I -- I don't --

15:16:33 20 This is dealing with, as I understand it, as
15:16:38 21 I recall, Northumbria, --

15:16:39 22 Q. Yeah.

15:16:40 23 A. -- which includes, what, about three
15:16:43 24 hospitals I think.

15:16:43 25 Q. Three hospitals, that's correct.

15:16:45 1 A. And one of them being Wansbeck.

15:16:47 2 Q. That's correct.

15:16:47 3 A. And so if they're making a policy with --

15:16:51 4 with regard to their group of hospitals, then I

15:17:00 5 would --

15:17:00 6 Was what you're suggesting is Wansbeck is

15:17:03 7 going outside of their --

15:17:04 8 Q. Ahead of the curve.

15:17:06 9 A. It's -- I guess it's conceivable.

15:17:08 10 Q. That's how law works with respect to the

15:17:10 11 federal government and states; correct? States can

15:17:13 12 implement rights that are more progressive than what

15:17:15 13 the federal government has promulgated; correct?

15:17:18 14 A. They -- they can. Whether hospitals --

15:17:21 15 hospital groups function that much, I -- I just don't

15:17:26 16 know that much about the hospitals in -- in -- in the

15:17:30 17 U.K.

15:17:31 18 Q. Okay.

15:17:31 19 A. I mean this took place in, what was it,

15:17:40 20 2008, '10, in that area, and when was Reed's

15:17:43 21 testimony?

15:17:44 22 Q. His deposition testimony?

15:17:45 23 A. His deposi -- yeah.

15:17:47 24 Q. 2016.

15:17:49 25 A. '16. So I mean he's recalling things, you

15:17:52 1 know, what, seven or eight years ago. It seems
15:18:01 2 possible that he misremem -- didn't remember it quite
15:18:06 3 right.

15:18:06 4 Q. Well this document was published in 2014;
15:18:10 5 correct? October for that matter.

15:18:11 6 A. Yeah, but -- well it -- this is a --
15:18:14 7 Gillson and Lowdon were writing this in the
15:18:18 8 leisure of their office. They weren't under
15:18:21 9 deposi -- under pressure of being under a
15:18:23 10 deposition --

15:18:23 11 Q. Okay.

15:18:24 12 A. --- and having to come up with answers off
15:18:25 13 the top of your head.

15:18:26 14 Q. Okay. So let's just --

15:18:27 15 I think we need to cut to it. There's
15:18:29 16 nothing in this doc -- document that necessarily
15:18:33 17 contradicts Mr. Reed's testimony.

15:18:35 18 A. It may not.

15:18:36 19 Q. It may not.

15:18:37 20 A. Yeah. It -- it --

15:18:38 21 Yeah, it may or may not. I --

15:18:39 22 Q. Is there any other evidence you relied on,
15:18:43 23 apart from that document, to surmise that there was
15:18:48 24 full reporting before July 1st, 2008 or after July
15:18:52 25 1st, 2008?

15:18:53 1 A. Well these -- these data -- I mean that --

15:18:58 2 The Albrecht 10, as I understand it, was not

15:19:02 3 the routine way in which a lot of these data were

15:19:06 4 collected, that they had to go back to the hospitals

15:19:08 5 and add a lot of the variables that they did, and so

15:19:12 6 in doing that, well, they went back to -- what was

15:19:15 7 it --

15:19:19 8 Q. Sometime in 2007.

15:19:21 9 A. -- sometime in 2007, whatever it was, well

15:19:24 10 before Mr. July 2008.

15:19:27 11 Q. But based on Mr. Reed's testimony, you do

15:19:30 12 not know --

15:19:30 13 A. Based on the testimony --

15:19:32 14 Q. -- whether it was a complete data set prior

15:19:34 15 to July 1st, 2008. You don't know.

15:19:36 16 A. Well was he talking about Albrecht 10? I

15:19:38 17 don't know.

15:19:41 18 Q. I'm talking about reconstruct --

15:19:44 19 A. I know what you're talking about, --

15:19:45 20 Q. Yeah.

15:19:46 21 A. -- but I'm not sure what Reed is talking

15:19:48 22 about.

15:19:49 23 Q. Talking about Wansbeck Hospital; correct?

15:19:52 24 A. Okay. But he --

15:19:53 25 MR. GORDON: Object to the form of the

15:19:54 1 question.

15:19:54 2 A. Was he talking about the data in Albrecht
15:19:56 3 10? I just -- I don't remember, frankly.

15:20:03 4 Q. Okay. Did you make any inquiry separate and
15:20:13 5 apart from the Gillson document about when full
15:20:16 6 reporting began at Wansbeck?

15:20:18 7 A. No.

15:20:19 8 Q. And you didn't ask 3M for any documents on
15:20:34 9 the subject matter.

15:20:37 10 A. No.

15:20:37 11 Q. And they provided no such documents on the
15:20:39 12 subject matter.

15:20:41 13 A. Not of when the -- on the -- on those
15:20:44 14 procedures, yeah.

15:20:45 15 Q. Okay.

15:20:45 16 A. They didn't.

15:20:46 17 Q. So your opinion as to the table that you
15:20:49 18 provided is based on Albrecht Exhibit 10 and that's
15:20:53 19 it.

15:20:54 20 A. That's right.

15:20:54 21 Q. Okay. With respect to Fig. 2, you provide
15:21:00 22 time trend data and there is a moving average line
15:21:03 23 which is the solid blue line; correct?

15:21:04 24 A. Yes.

15:21:05 25 Q. And that line -- or that data also begins in

15:21:09 1 2007; correct?

15:21:10 2 A. That's right.

15:21:11 3 Q. And it begins on September 1st, 2007, which
15:21:15 4 is approximately 10 months before the McGovern study
15:21:19 5 period; correct?

15:21:20 6 A. Yes.

15:21:21 7 Q. And that data also depends on Albrecht
15:21:23 8 Exhibit 10; correct?

15:21:24 9 A. Yes.

15:21:26 10 Q. And with respect to the first spike in this
15:21:30 11 figure, if you took away the data prior to July 1st,
15:21:35 12 2008, wouldn't be much of a spike; correct?

15:21:41 13 A. Well it's sort of -- yeah. In the earlier
15:21:43 14 data there was really very little going on, the rates
15:21:46 15 were very, very low. Bair Hugger was being used, as I
15:21:49 16 understand it, but the infection rates were extremely
15:21:53 17 low.

15:21:53 18 Q. And to the extent that there was incomplete
15:21:55 19 data prior to July 2007, that would explain the low
15:21:59 20 rates; correct?

15:21:59 21 MR. GORDON: Objection, assumes facts not in
15:22:02 22 evidence.

15:22:04 23 A. I mean the reason there were no -- there
15:22:10 24 were very few in -- infections -- I mean I don't -- I
15:22:14 25 don't know. There were very few reported in the -- in

15:22:17 1 the data file.

15:22:17 2 Q. In Albrecht Exhibit 10.

15:22:19 3 A. Yes.

15:22:21 4 Q. And the green line is the constant average
15:22:27 5 of deep joint infection in the Bair Hugger period and
15:22:30 6 the Hot Dog period; correct?

15:22:31 7 A. That's right.

15:22:31 8 Q. And that is also based on Albrecht Exhibit
15:22:34 9 10; correct?

15:22:34 10 A. Yes.

15:22:35 11 Q. So instead of an infection rate of 3.0, your
15:22:37 12 infection rate with respect to the Bair Hugger period
15:22:39 13 is 2.91.

15:22:41 14 A. Something like that.

15:22:43 15 Q. Okay.

15:22:43 16 A. Looks about right.

15:22:48 17 Q. And the Hot Dog rate, instead of being .8
15:22:53 18 percent, is 1.08 percent; correct?

15:22:57 19 A. That sounds about right, and it looks about
15:23:01 20 right from the -- from the graph.

15:23:02 21 Q. And that's based on using four Hot Dog
15:23:04 22 infections instead of three Hot Dog infections;
15:23:07 23 correct?

15:23:07 24 A. That's correct.

15:23:08 25 Q. And that derives from Albrecht Exhibit 10;

15:23:10 1 correct?

15:23:10 2 A. Yes.

3 Q. Okay.

15:23:12 4 MR. GORDON: Well --

15:23:12 5 Q. The broken blue line --

15:23:14 6 A. Well it depends on --

15:23:16 7 I mean the four also comes from the -- from

15:23:19 8 the deposition by Reed where he reports that there was

15:23:23 9 one more in -- one more infection for --

15:23:27 10 Well, he reports one more in each group.

15:23:29 11 Q. Okay. But you don't ever, aside from

15:23:32 12 footnote one, assume that there is one more infection

15:23:34 13 in the Bair Hugger period; correct?

15:23:38 14 MR. GORDON: Object to the --

15:23:40 15 A. That's --

15:23:40 16 Well I -- I mean I used -- used Exhibit 10.

15:23:43 17 Q. Yes. But you just --

15:23:45 18 A. I mean, again, we've been talking about

15:23:47 19 Reed --

15:23:47 20 Q. Uh-huh.

15:23:47 21 A. -- and it seems quite possible that Reed

15:23:55 22 was, you know, retrospectively recalling what took

15:24:02 23 place, --

15:24:02 24 Q. Uh-huh. And Reed --

15:24:04 25 A. -- and so he said there was one more.

15:24:06 1 Q. Uh-huh.

15:24:06 2 A. Well, I wouldn't accuse him of lying if
15:24:10 3 there in fact was one more in one group and one less
15:24:13 4 in the other.

15:24:14 5 Q. Okay. If you wouldn't accuse him of lying,
15:24:16 6 you didn't rely on those numbers at any place in your
15:24:19 7 report other than footnote one; correct?

15:24:21 8 A. Other than footnote -- footnote one, yeah.
15:24:23 9 Footnote one is basically where I --

15:24:25 10 Q. That's the full extent.

15:24:26 11 A. That's right. I took -- I took -- took him
15:24:29 12 at his word and --

15:24:29 13 Q. Okay.

15:24:31 14 A. -- used those values.

15:24:31 15 Q. So with respect to the statement you made
15:24:33 16 prior to that, you're relying on Reed with respect to
15:24:37 17 four Hot Dog infections but not 32 or 33 Bair Hugger
15:24:40 18 infections, only 31 Bair Hugger infections.

15:24:43 19 A. Well the numbers -- the numbers that were
15:24:45 20 used in that tabulation were the numbers that I got
15:24:48 21 from -- from the -- from Albright 10 --

15:24:51 22 Q. Yeah.

15:24:52 23 A. -- and --

15:24:54 24 Q. Which is inconsistent with Reed's testimony;
15:24:57 25 correct?

15:24:57 1 A. It's inconsistent.

15:24:58 2 Q. Yeah.

15:24:59 3 A. Yeah. It's the -- it's -- it's --

15:25:02 4 I think it's the same for Hot Dog, but it's
15:25:05 5 inconsistent for Bair Hugger.

15:25:07 6 Q. Well Reed says four infections Hot Dog, 33
15:25:11 7 infections Bair Hugger; correct? One more in each
15:25:14 8 group.

15:25:16 9 A. That's what -- that's what he said.

15:25:18 10 Q. Yeah.

15:25:19 11 A. Yeah.

15:25:19 12 Q. And the --

15:25:19 13 A. But -- but the tab -- but --

15:25:21 14 But Albright 10 --

15 15 Q. Yeah.

15:25:22 16 A. -- says four and 31.

15:25:24 17 Q. But you wouldn't assume, like you just said,
15:25:26 18 that Reed would be lying; right?

15:25:27 19 A. No. I just -- I -- I would guess that
15:25:30 20 he's -- that he's not remembering things. I mean as
15:25:37 21 we -- as you notice, he's reporting on -- he's talking
15:25:41 22 about something in his deposition about eight --

15:25:42 23 Q. Yeah.

15:25:43 24 A. -- seven or eight years later, and he may
15:25:46 25 not remember --

15:25:46 1 Q. Okay.

15:25:47 2 A. -- things quite right.

15:25:48 3 Q. But with respect to the four infections and
15:25:50 4 33 infections, that might be true, but it may not be
15:25:54 5 true that the start date was July 1st, 2008.

15:25:58 6 A. Yeah. I mean if he mis -- if he
15:26:01 7 misremembered one, it's possible he misremembered the
15:26:03 8 other as well.

15:26:04 9 Q. Okay.

15:26:04 10 A. I mean I -- I don't know.

15:26:06 11 Q. But you don't know.

15:26:06 12 A. I --

15:26:08 13 No, I don't know. I don't know. If you
15:26:10 14 asked me what I was doing --

15:26:12 15 Q. Yeah.

15:26:12 16 A. -- in July 2008, I don't think I could tell
15:26:15 17 you very accurately.

15:26:16 18 Q. Had you relied on Reed's testimony regarding
15:26:19 19 the four infections in the Hot Dog group and the 33
15:26:22 20 infections in the Bair Hugger group, all of the
15:26:24 21 calculations in your report would be different;
15:26:27 22 correct?

15:26:27 23 MR. GORDON: Object to the form of the
15:26:28 24 question, assumes facts not in evidence.

15:26:31 25 A. Yeah. I'm not sure what --

15:26:34 1 Q. I can re -- I'll rephrase.

15:26:36 2 Your calculation derives from four Hot Dog
15:26:40 3 infections and 31 Bair Hugger infections; correct?

15:26:43 4 A. Yeah. Well, which derives from Albrecht 10.

15:26:48 5 Q. Albrecht 10.

15:26:49 6 A. Yes.

15:26:49 7 Q. And there's no reason to suspect that Reed
15:26:51 8 was lying. He testified that there was four Hot Dog
15:26:53 9 infections and 33 Bair Hugger infections, and if that
15:26:57 10 is true, that would change all of the calculations in
15:26:59 11 your report; correct?

15:27:02 12 A. It would change many of them. I mean
15:27:05 13 ideally what I would like to know is why -- what --
15:27:08 14 what the correct --

15:27:10 15 While Reed may not remember exactly what
15:27:21 16 took place, what -- what the -- what the values were,
15:27:26 17 I think he's -- he's suggesting that there -- there
15:27:30 18 was an error in the data that are published in
15:27:35 19 McGovern.

15:27:36 20 Q. And assuming that to be true, one of those
15:27:39 21 errors is actually there was more Bair Hugger
15:27:41 22 infections.

15:27:43 23 A. And more -- I mean he --

15:27:47 24 One of the things he is conceding is that
15:27:49 25 there is more -- there -- there's one more Hot Dog

15:27:56 1 infection.

15:27:57 2 Q. But you took into account --

15:27:59 3 A. Because there's -- because there's so few,
15:28:01 4 there's only three, --

5 Q. Yeah.

15:28:02 6 A. -- you're going from three to four, so
15:28:04 7 that's a 33 percent difference, so that's having a
15:28:07 8 much bigger effect on your estimates of risk than the
15:28:13 9 change of one or two in the -- in the -- in the Bair
15:28:18 10 Hugger.

15:28:18 11 Q. But you never used that data with respect to
15:28:21 12 the Bair Hugger; correct?

15:28:23 13 MR. GORDON: Objection.

15:28:23 14 Q. You only used the four hundred -- or the
15:28:25 15 four Hot Dog infections and only used 33 Bair Hugger
15:28:28 16 infections in footnote one of your report; correct?

15:28:31 17 A. That's the only place -- that's the only
15:28:33 18 place I -- I change it in my report.

15:28:35 19 Q. Okay.

15:28:36 20 A. Yeah.

15:28:36 21 Q. Okay.

15:28:36 22 A. I mean ideally what I would like to know, as
15:28:39 23 this implies, that there is -- that -- for Albrecht
15:28:45 24 10, and to be consistent, I would like to get it
15:28:50 25 consistent with -- with Reed.

15:28:52 1 Q. And you can't.

15:28:54 2 A. Not as they're given.

15:28:55 3 Q. Okay.

15:28:56 4 A. They would have to sit down and somehow make
15:28:58 5 a correction, either --

15:29:03 6 Well either Reed is right or -- or Albrecht
15:29:07 7 10 is -- is right on this particular question, and it
15:29:11 8 would be good if -- it would be nice if I could sit
15:29:15 9 down and they could correct what this -- what
15:29:18 10 the -- what the -- what the discrepancy is.

15:29:20 11 Q. And you --

15:29:20 12 A. There is a discrepancy.

15:29:21 13 Q. And you don't know.

15:29:23 14 A. And I don't know why there is a discrepancy.

15:29:24 15 Q. And you don't know which one it might be.

15:29:28 16 A. I don't know. I mean in looking at a file
15:29:31 17 that looks like a raw data set gives me at bit more
15:29:34 18 confidence than someone remembering something eight
15:29:38 19 years ago. But in any event, it needs -- well
15:29:45 20 someone --

15:29:45 21 Ideally, someone would sit down with these
15:29:48 22 data and, you know, review it with the -- with the raw
15:29:52 23 records and -- and -- to correct whatever -- whatever
15:29:55 24 it is.

15:29:56 25 Q. It could also be neither.

15:29:58 1 A. That neither one was right?

15:30:00 2 MR. GORDON: Object to the form of the
15:30:01 3 question, assumes facts not in evidence, calls for
15:30:03 4 speculation.

15:30:03 5 Q. I mean the published data is neither one of
15:30:06 6 those two. Correct?

15:30:07 7 A. It's neither one of them.

15:30:08 8 MR. GORDON: Same objection.

15:30:09 9 Q. Right. It's -- it's neither Albrecht 10 --

15:30:11 10 A. Oh, I see. Yeah.

15:30:12 11 Q. -- nor Reed's testimony.

15:30:14 12 A. Yeah. I mean if it's -- yeah, if you're
15:30:17 13 going --

15:30:17 14 Q. On the published data.

15:30:20 15 A. Yeah. If the published data is -- is
15:30:22 16 correct --

15:30:22 17 Q. Okay.

15:30:23 18 A. -- and there's -- I mean, you know, there's
15:30:25 19 some doubt, obviously, but --

15:30:28 20 Q. Let's move to the confounding portion of
15:30:32 21 your report. And I'd like to establish a definition
15:30:40 22 of "confounding," which I'll phrase as a variable C is
15:30:45 23 a confounder if it is related to disease and also
15:30:48 24 related to exposure. Do you agree with that?

15:31:00 25 A. State that again.

15:31:01 1 Q. A variable C is a confounder if it is
15:31:04 2 related to disease and also related to exposure.

15:31:11 3 A. If -- if it is related to disease and it's
15:31:18 4 related to the exposure --

15:31:24 5 We're not saying statistically significant;
15:31:27 6 right?

15:31:27 7 Q. Yeah. I'm just --
15:31:28 8 Just for this definition.

15:31:29 9 A. Yeah. If that --
15:31:31 10 If those are true, then it is a confounder.

15:31:33 11 Q. That's how you defined it in your article
15:31:35 12 "Confounding in Epidemiological Studies" which was
15:31:40 13 published in Biometrics; correct?

15:31:44 14 A. Oh. Oh, right, right. Yeah, that's -- I --
15:31:47 15 I didn't remember which -- trying to remember which
15:31:50 16 article you were talking about. Yeah.

15:31:52 17 Q. By Wickramaratne --

18 A. Oh, okay.

15:31:55 19 Q. -- and you.

15:31:56 20 A. Not the --

15:31:57 21 Okay. Yeah, yeah, yeah, yeah.

15:31:58 22 Q. That's how you defined it.

15:32:00 23 A. Okay.

15:32:01 24 Q. And according to Dr. Borak, differently
15:32:03 25 stated, a variable must be an independent risk factor

15:32:06 1 for it to be a confounder on the outcome; correct?

15:32:11 2 MR. GORDON: Well object, foundation.

15:32:14 3 A. Yeah. It needs to be a risk --

15:32:18 4 It needs to have an association.

15:32:19 5 Q. Okay. And if there's no such association to
15:32:23 6 the outcome, it's not a confounder; correct?

15:32:28 7 A. That's right. I'm not eliminating it, of
15:32:31 8 course.

15:32:31 9 Q. Yeah. I know what you said before, but --

15:32:33 10 A. Again, I'm not saying --

15:32:34 11 Q. -- if there's no a priori relationship, it's
15:32:37 12 not a confounder.

15:32:37 13 A. Yeah. And we're talking about statis --

15:32:40 14 We're not talking about statistics.

15:32:41 15 Q. An a priori relationship.

16 A. Yeah.

15:32:43 17 Q. If there's an a priori --

15:32:44 18 If there's not an a priori relationship
15:32:45 19 between a variable and an outcome, it's not a
15:32:48 20 confounding factor.

15:32:49 21 A. That's right. Adjusted for the -- adjusted
15:32:52 22 for each other, yeah.

15:32:53 23 Q. Okay. Are you aware that thromboprophylaxes
15:33:02 24 are used for reducing the risk of blood clotting?

15:33:09 25 A. I -- yeah. I think so, yeah. Yeah.

15:33:11 1 Q. The point of using --

15:33:13 2 A. Yeah.

15:33:13 3 Q. -- a thromboprophylaxis, whether it be
15:33:16 4 tinzaparin or Xarelto or any other low-molecular-
15:33:23 5 weight heparin, is to reduce the incidence of venous
15:33:27 6 thrombosis; right?

15:33:28 7 A. Okay. I'm not a clinician, but --

15:33:31 8 Q. So you're not a clinician but you're
15:33:33 9 assuming there's an a priori relationship between
15:33:37 10 thrombo and other outcomes separate and apart from
15:33:40 11 deep vein thrombosis?

15:33:43 12 A. Well what you're asking for is a -- is a
15:33:46 13 particular relationship, which is not --

15:33:48 14 I mean there are lots of drugs that are
15:33:50 15 related to more than one thing.

15:33:52 16 Q. Okay.

15:33:53 17 A. So the fact that that's what it is used for
15:33:57 18 does not mean it does not -- does or does not have
15:33:59 19 another effect.

15:34:00 20 Q. Okay. Do you know how thromboprophylaxes
15:34:03 21 are administered?

15:34:04 22 A. No.

15:34:05 23 Q. You're not aware that Xarelto is
15:34:08 24 administered postoperatively.

15:34:10 25 A. No.

15:34:12 1 Q. You're not aware that tinzaparin is also
15:34:16 2 often administered postoperatively.

15:34:18 3 A. I didn't know how they were operate -- they
15:34:22 4 were --

15:34:22 5 Q. You didn't read that in the McGovern study?

15:34:23 6 A. I probably did. I wasn't --

15:34:24 7 I mean they were using it in the Jensen
15:34:29 8 study, they were using it and comparing it and looking
15:34:37 9 at it for an effect with -- with infections.

15:34:41 10 Q. Understood. But you're aware that the
15:34:43 11 McGovern study, the patients received the
15:34:46 12 thromboprophylaxis postoperatively.

15:34:49 13 A. Okay.

15:34:51 14 Q. Okay. So the thromboprophylaxis does not
15:34:54 15 add particles to the surgical site; correct?

15:34:58 16 A. Presumably not.

15:34:59 17 Q. It doesn't add bacteria to the surgical
15:35:01 18 site; correct?

15:35:03 19 A. No.

15:35:09 20 Q. Xarelto is approved by The American College
15:35:11 21 of Chest Physicians. Do you know that?

15:35:14 22 MR. GORDON: Objection, lack of foundation.

15:35:16 23 A. Xarelto is which one now?

15:35:18 24 Q. Rivaroxaban.

15:35:20 25 A. Rivaroxaban. Okay.

15:35:23 1 Q. It is.

15:35:23 2 A. Okay. I don't --

15:35:23 3 I was not aware of that. I --

15:35:25 4 Q. Okay. Have you studied the record trials?

15:35:29 5 A. No, I have not.

15:35:30 6 Q. You're not aware that there were five
15:35:32 7 randomized controlled trials that evaluated the safety
15:35:35 8 of rivaroxaban, otherwise known as Xarelto, in
15:35:40 9 orthopedic surgeries?

15:35:41 10 A. No, I'm not familiar with that.

15:35:44 11 Q. You're not aware that one of the studies
15:35:46 12 concluded that the clinical efficacy and safety of
15:35:52 13 rivaroxaban after elective hip and knee arthroplasty
15:35:58 14 has been established in the four randomized controlled
15:36:00 15 trials of the regulation of coagulation in orthopedic
15:36:03 16 surgery to prevent deep vein thrombosis.

15:36:07 17 A. I was not familiar with that.

15:36:11 18 Q. Did you attempt to investigate whether
15:36:16 19 thromboprophylaxes have been deemed to be safe in
15:36:20 20 orthopedic surgeries?

15:36:20 21 A. No. I was -- I was looking at -- well the
15:36:26 22 same -- the evidence that -- that McGovern cited as --
15:36:36 23 He was citing the -- the work that was done
15:36:38 24 by -- the paper by Jensen I believe.

15:36:42 25 Q. So the only basis for an a priori assumption

15:36:46 1 that the use of Xarelto is related to the outcome of
15:36:50 2 interest; namely, deep joint infection, is the Jensen
15:36:54 3 study?

15:36:55 4 A. That was, my understanding, the basis on
15:36:58 5 which they did not control for it.

15:37:00 6 Q. And my question is a little different. Your
15:37:03 7 basis for making an a priori assumption that Xarelto
15:37:08 8 is related to the outcome of interest, which is deep
15:37:12 9 joint infection, is only the Jensen study.

15:37:17 10 A. That's what I was looking -- looking for.
15:37:21 11 McGovern did not control for any
15:37:26 12 confounding.

15:37:26 13 Q. I understand. My question again, which I
15:37:28 14 think you answered, is that the only piece of
15:37:32 15 evidence --

16 A. Yes.

15:37:33 17 Q. -- that you considered as to whether there
15:37:34 18 is an --

19 A. I was --

15:37:34 20 Q. -- a priori relationship between Xarelto and
15:37:37 21 the outcome of interest, which is deep joint
15:37:39 22 infection, is the Jensen study. True or false? It's
15:37:42 23 a one-word answer.

15:37:43 24 A. Yeah. Well I wasn't saying it was a priori.
15:37:47 25 I was looking at the data --

15:37:48 1 Q. Okay.

15:37:49 2 A. -- to see whether or not there was an
15:37:50 3 association.

15:37:51 4 Q. Is that the only study that you looked at?

15:37:53 5 A. Well I was using --

15:37:58 6 I referred to that study because that was
15:38:01 7 the study that McGovern referred to.

15:38:03 8 Q. Did you look at any other studies?

15:38:04 9 A. I didn't look at any other studies. I had
15:38:08 10 be --

15:38:08 11 The data on which the Jensen paper was --
15:38:17 12 was based, I mean the design is basically the same
15:38:21 13 sort of --

15:38:23 14 Q. The same design as in McGovern.

15:38:25 15 A. Yeah. It's the same flawed design that
15:38:28 16 McGovern used, which is based on dates.

15:38:30 17 Q. Okay. But my question again is did you look
15:38:34 18 at any other studies?

15:38:35 19 A. And so I could repeat -- I could repeat the
15:38:37 20 analysis --

15:38:37 21 Q. Okay. We'll get there. Trust me, we'll get
15:38:41 22 there.

15:38:41 23 A. -- that -- that they did using Albrecht 10.

15:38:44 24 Q. Okay. So in other words, your only basis
15:38:49 25 for concluding that the thromboprophylaxis may or may

15:38:53 1 not be a confounder is based on the data from Albrecht
15:38:55 2 Exhibit 10.
15:38:56 3 A. Yes.
15:39:01 4 Q. You conducted no investigation to determine
15:39:04 5 whether the peer-reviewed public literature had
15:39:06 6 determined that Xarelto was safe in orthopedic
15:39:09 7 surgeries.
15:39:10 8 A. No.
15:39:16 9 Q. And the Jensen study, which appears to be
15:39:25 10 the source that you rely on with application of
15:39:29 11 Albrecht Exhibit 10, in fact found that there was not
15:39:33 12 a significant difference between deep joint infection
15:39:36 13 rates from the use of Xarelto compared to tinzaparin;
15:39:41 14 correct?
15:39:41 15 A. They did not find a statistical
15:39:43 16 significance.
15:39:43 17 Q. That's the scope of the question.
15:39:45 18 A. That's right.
15:39:45 19 Q. And the p-value wasn't even close to
15:39:49 20 significant; correct?
15:39:51 21 A. Yes. The p-value was --
15:39:53 22 Yeah.
15:39:54 23 Q. Do you know what it was?
15:39:56 24 A. I think somewhere around .11 or something.
15:39:58 25 I don't remember.

15:39:59 1 Q. .7 ring a bell?

15:40:01 2 A. .7?

15:40:02 3 Q. Yeah.

15:40:03 4 MR. GORDON: Maybe you should look at the

15:40:04 5 article.

15:40:06 6 A. Yeah. That seems high. I --

15:40:12 7 Do you have the article?

15:40:14 8 Q. We have marked the article as a prior

15:40:17 9 exhibit, and I can tell you what it is in a moment.

15:40:24 10 MR. GORDON: I'm look --

15:40:26 11 Nineteen.

15:40:26 12 A. Here. Oh, I'm --

15:40:28 13 MR. GORDON: Exhibit 19.

15:40:32 14 Q. If you turn to page 523 on the bottom right,

15:40:37 15 or internal page 93, there's a section entitled

15:40:40 16 "Results;" correct?

15:40:44 17 Of the Jensen study.

15:40:44 18 A. Do I have --

15:40:44 19 Q. Oh, okay.

15:40:45 20 MR. GORDON: It's Exhibit 19.

15:40:46 21 Q. Exhibit 19, professor.

15:40:48 22 A. Nineteen.

15:40:55 23 MR. GORDON: That's it.

15:40:58 24 Q. Okay. If you turn to page 523, in the

15:40:59 25 bottom right-hand corner --

15:41:00 1 A. Okay.

15:41:01 2 Q. -- on the left column is a section entitled
15:41:03 3 "Results;" correct?

15:41:04 4 A. Yes.

15:41:06 5 Q. Do you see the third paragraph that says,
15:41:06 6 "Of those...?"

15:41:07 7 A. Yeah.

15:41:07 8 Q. It says, "Of those patients who returned to
15:41:10 9 theatre, microbiology results showed that five of the
15:41:15 10 nine (55.5 percent) in group 1 had a deep infection,
15:41:16 11 compared with 14 of 22 (63.6 percent) in group 2 (p
15:41:20 12 equals 0.7)."

15:41:23 13 A. Okay.

15:41:23 14 Q. Does that refresh your recollection --

15:41:24 15 MR. GORDON: Well why don't you read the
15:41:26 16 rest of the section that actually talks about deep
15:41:29 17 infection.

15:41:29 18 THE WITNESS: Yeah.

15:41:29 19 Q. "The overall rate of deep infection in group
15:41:33 20 1 was one percent, compared with 2.5 percent in group
15:41:34 21 2" with a p-value of .1.

15:41:36 22 A. Right. So that's what I was --

15:41:37 23 Q. Is that the p-value of interest or is it the
15:41:41 24 .7?

15:41:41 25 A. I was thinking it was --

15:41:43 1 You're com -- you're comparing the deep

15:41:44 2 infection rate --

15:41:45 3 Q. Okay.

15:41:46 4 A. -- between the two, and so that was the

15:41:48 5 comparison that I was looking at, because we were

15:41:50 6 looking at deep -- you know, deep infection rates in

15:41:56 7 McGovern.

15:41:57 8 And of course the definition of "deep

15:42:01 9 infection" is different in Jensen's paper than it is

15:42:04 10 in McGovern.

15:42:06 11 Q. It was a 30-day period whereas in --

12 A. Thirty days --

15:42:08 13 Q. -- McGovern it was a 60-day period; correct?

15:42:10 14 A. Exactly.

15:42:10 15 Q. Okay.

15:42:11 16 A. So there are some -- going to be some more

15:42:14 17 infections in -- if -- I -- I --

15:42:18 18 I went on and I used the McGovern

15:42:21 19 definition.

15:42:21 20 Q. Yeah. For both arms of the study; correct?

15:42:23 21 A. For -- for -- that's right, for the -- for

15:42:25 22 Jensen.

15:42:26 23 Q. So there could be more infections in the

15:42:28 24 Bair Hugger group and there could be more infections

15:42:30 25 in the Hot Dog group.

15:42:31 1 A. Exactly.

15:42:32 2 Q. Okay. In addition to the Jensen study, did
15:42:34 3 you review the Reed study that also analyzed whether
15:42:39 4 there was a significant increase in deep joint
15:42:42 5 infection rates from the use of a low-molecular-weight
15:42:47 6 heparin to Xarelto?

15:42:48 7 A. I don't know that I looked at that much.

15:42:51 8 Q. It was cited by Dr. Samet; correct?

15:42:53 9 A. It -- it may have been. I -- I'm just not
15:42:57 10 re --

15:42:57 11 I don't recall that one.

15:42:58 12 Q. I'll represent to you that it was cited
15:43:00 13 by --

15:43:00 14 A. Okay.

15:43:02 15 Q. -- Dr. Samet. You did not review that
15:43:04 16 article?

15:43:04 17 A. I don't recall reviewing that article, no.

15:43:06 18 Q. So to the extent that Dr. Samet relied on
15:43:09 19 that article in concluding that the change in
15:43:11 20 thromboprophylaxis was not a confounding factor, you
15:43:14 21 have not reviewed that study and therefore cannot
15:43:16 22 comment on it.

15:43:17 23 A. Well Samet was talking about looking at
15:43:20 24 effects and he was basing his conclusions on the
15:43:26 25 conclusion of the paper, which depended on statistical

15:43:28 1 significance, --

15:43:28 2 Q. Okay.

15:43:29 3 A. -- so he was looking at --

15:43:32 4 My understanding of Samet's statement was
15:43:35 5 on -- the basis of it was that they did not find that
15:43:38 6 it was statistically significant, --

15:43:39 7 Q. Okay.

15:43:40 8 A. -- and on that basis he -- he dismissed it.

15:43:43 9 Q. To the extent that others have concluded,
15:43:46 10 such as Dr. Reed in his deposition, --

15:43:47 11 A. Yeah.

15:43:48 12 Q. -- that Xarelto can be ruled out as a
15:43:51 13 confounding factor, do you have any basis to doubt
15:43:53 14 that statement?

15:43:56 15 A. Well I -- I mean we did -- we did the --
15:44:02 16 the -- we --

15:44:05 17 We talked about the reasons that a variable
15:44:10 18 is -- is a confounder, --

15:44:11 19 Q. Yeah.

15:44:12 20 A. -- and as I've -- as I've said, the -- the
15:44:18 21 reason for it being a confounder is that there is this
15:44:22 22 association with the exposure and with the outcome,
15:44:25 23 okay, and we've stipulated that that association may
15:44:29 24 not be statistically significant.

15:44:31 25 Q. We haven't stipulated, but you said that.

15:44:34 1 A. Well -- and I've --

15:44:36 2 In my report I referred to the work by --

15:44:38 3 the -- the textbook by --

15:44:43 4 Q. Breslow and Day.

15:44:45 5 A. -- Breslow and Day where they in fact show

15:44:48 6 example -- a counterexample of where that is in fact

15:44:50 7 true.

15:44:51 8 Q. That example related to cancer and age;

15:44:53 9 correct?

15:44:53 10 A. I've forgotten what the -- what the table

15:44:57 11 was, but --

15:44:58 12 Q. Okay.

15:44:58 13 A. -- it -- it doesn't really -- it doesn't

15:45:01 14 really matter. It was just illustrating the -- the

15:45:03 15 point --

15:45:04 16 Q. Okay.

15:45:04 17 A. -- that you could have -- you could have

15:45:07 18 associations that are not -- that don't achieve

15:45:10 19 statistical significance but they do in fact behave as

15:45:15 20 confounders in that they change the association when

15:45:19 21 you adjust for them. And it can go either way, it can

15:45:23 22 go -- make a very weak association stronger or it can

15:45:27 23 make a strong association go away.

15:45:29 24 Q. But you had said before that it's not always

15:45:32 25 necessary to control for a particular variable in the

15:45:35 1 event that it is not significantly related to the
15:45:39 2 outcome; correct?

15:45:42 3 A. You may need to control for it even if it is
15:45:45 4 not.

15:45:45 5 Q. The question was a little different. You've
15:45:47 6 said you do not need to control for a particular
15:45:52 7 variable in the event that there is not a significant
15:45:55 8 relationship between that variable and the outcome of
15:45:58 9 interest; correct?

15:46:00 10 A. No, I don't think that's quite what I --
15:46:03 11 what I said. I -- the --

15:46:12 12 When people are looking for confounders,
15:46:16 13 it's -- it's a tricky thing to look for it because
15:46:21 14 statistical significance is an easy thing for it to
15:46:25 15 sort of pop out, --

15:46:26 16 Q. Uh-huh.

15:46:26 17 A. -- but a confounding variable is does the
15:46:30 18 control for this variable change the magnitude of the
15:46:33 19 association that you're looking for, --

15:46:34 20 Q. Okay.

15:46:34 21 A. -- and so that's the relevant issue.

15:46:37 22 Q. We'll get -- we'll get there.

15:46:38 23 A. And that's -- and that's not what -- what --
15:46:41 24 what Samet seemed to be talking about in his
15:46:44 25 deposition.

15:46:45 1 MR. SACCHET: Okay. We'll get to the change
15:46:46 2 in relative risk in a minute, but first I'd like you
15:46:49 3 to, in just a moment, return -- turn your attention to
15:46:56 4 what will be marked as Exhibit --
15:46:59 5 THE REPORTER: Twenty-six.
15:46:59 6 MR. SACCHET: -- 26.
15:47:10 7 (Exhibit 26 was marked for
15:47:12 8 identification.)
15:47:12 9 BY MR. SACCHET:
15:47:15 10 Q. Is this a document regarding reader
15:47:18 11 reactions to your article entitled "Confounding in
15:47:23 12 Epidemiologic Studies?" Which you can see on page
15:47:29 13 1309, the first page of actual text of the document,
15:47:36 14 on the title. First page of text after the title
15:47:40 15 page.
15:47:52 16 A. Oh, this is -- okay.
15:47:54 17 Q. Have you seen this document before?
15:47:55 18 A. Yes, I have.
15:47:57 19 Q. Okay. And you indeed published an article
15:48:00 20 called "Confounding in Epidemiologic Studies;"
15:48:05 21 correct, in 1989 --
15:48:06 22 A. Yes.
15:48:06 23 Q. -- in Biometrics?
15:48:08 24 A. Nineteen --
15:48:13 25 Well I think this is referring -- this

15:48:16 1 appeared in --

15:48:17 2 Isn't this referring to the Wickramar --

15:48:22 3 Wickramaratne --

15:48:22 4 Q. Yes.

15:48:23 5 A. -- paper in '87?

15:48:24 6 Q. Okay. And you were a co-author of that

15:48:27 7 paper; correct?

15:48:28 8 A. Yes, I am.

15:48:28 9 Q. Okay. So as you can see on the first page

15:48:30 10 of text at 1309, Sander Greenland from the Department

15:48:33 11 of Epidemiology at UCLA --

15:48:36 12 A. Yeah.

15:48:36 13 Q. -- provides a reader reaction; correct?

15:48:38 14 A. Yes.

15:48:39 15 Q. On page 1310, Paul Holland from Princeton,

15:48:43 16 New Jersey also provides a reader reaction; correct?

15:48:46 17 A. Yes.

15:48:54 18 Q. And on page 1317, Professor Mantel from

15:49:01 19 American University provides a review as well;

15:49:05 20 correct?

15:49:05 21 A. Yes.

15:49:06 22 Q. Professor Mantel is a notable statistician;

15:49:09 23 correct?

15:49:09 24 A. Yes, he is. Was.

15:49:11 25 Q. Oh. Okay. I didn't know that.

15:49:13 1 And on page 1319 you provide a response.

15:49:19 2 A. Yes.

15:49:21 3 Q. And if you go to the paragraph on 1319
15:49:27 4 beginning with "Mantel," do you see it says "Mantel
15:49:30 5 raises...?"

15:49:30 6 A. Yeah.

15:49:30 7 Q. And it says, "Mantel raises the important
15:49:32 8 question often facing the applied statistician of what
15:49:35 9 to do when faced with the analysis or design of a
15:49:38 10 particular study." Do you see that?

15:49:39 11 A. Yes.

15:49:40 12 Q. I'm going to skip the next sentence and then
15:49:42 13 say, "Reasons given by Mantel for covariate adjustment
15:49:47 14 are '...to reduce bias and to increase precision.'
15:49:49 15 The particular example described by Mantel involves
15:49:53 16 age as a potential confounder for cancer, a situation
15:49:55 17 in which there is no question of whether there is in
15:49:58 18 fact association. However, in other situations, one
15:50:01 19 must decide whether to adjust on an empirical basis,
15:50:05 20 and in these instances it was not always obvious how
15:50:08 21 one should behave."

15:50:10 22 That's what you wrote; correct?

15:50:11 23 A. Yes.

15:50:11 24 Q. You then say, "Statistical significance is
15:50:15 25 not always the best guide as to which variables are

15:50:18 1 confounders by any reasonable criterion, as was
15:50:24 2 elegantly pointed out in an example given by Breslow
15:50:24 3 and Day;" correct?

15:50:25 4 A. Yes.

15:50:25 5 Q. Why didn't you say it never is?

15:50:31 6 A. Well it could be.

15:50:34 7 Q. So in the event that there is not
15:50:38 8 statistical significance between two variables, there
15:50:41 9 may be no need to control as to whether that variable
15:50:45 10 is a confounder?

15:50:48 11 A. Well you could have an association that is
15:50:55 12 not statistically significant but it is important to
15:50:59 13 control because it -- because your estimate of
15:51:04 14 association is biased if you don't control it.

15:51:07 15 Q. But you may also have a situation in which
15:51:10 16 the variable is non-significant to an outcome and you
15:51:13 17 shouldn't control; correct?

15:51:16 18 A. No. It -- it has nothing to -- it's --
15:51:20 19 the --

15:51:21 20 The point is -- the point I was making
15:51:23 21 before is that -- is are -- is that statistical
15:51:26 22 significance is not necessarily the criteria you
15:51:32 23 should be looking at.

15:51:34 24 Q. For confounding.

15:51:35 25 A. For confounding. You could have

15:51:38 1 assoc -- I mean it's not -- it could --

15:51:41 2 The reason it's not statistically

15:51:43 3 significant could be that there is no association,

15:51:47 4 okay, and that's in fact the criteria that -- that --

15:51:52 5 that -- that's what's needed for there to be --

15:51:58 6 Well, if there is no association, then it --

15:52:03 7 then there is no confounding.

15:52:04 8 Q. Okay.

15:52:05 9 A. But there could be an association, it's just

15:52:08 10 that that association -- you don't have enough power

15:52:10 11 to -- to determine if that association -- for that

15:52:14 12 association to be statistically significant.

15:52:16 13 Q. Okay.

15:52:17 14 A. And so in that case, you shouldn't make your

15:52:22 15 choice based on the statistical significance but

15:52:27 16 whether or not it actually does make a change in

15:52:29 17 the -- in the effect.

15:52:30 18 Q. Okay. And that's what you mean when you go

15:52:32 19 on to say, "In this instance, the potential confounder

15:52:35 20 was not significantly associated with disease, and yet

15:52:38 21 the inference on the disease factor association was

15:52:40 22 quite different depending on whether one controlled

15:52:43 23 for the confounding variable in the analysis."

15:52:45 24 A. Yes.

15:52:45 25 Q. Correct?

15:52:46 1 A. Uh-huh.

15:52:46 2 Q. Okay. So the bottom line is whether or not
15:52:50 3 something is significant, you should look at whether
15:52:53 4 the odds ratio changes based on the uncontrolled
15:52:57 5 calculation and the controlled calculation; correct?

15:52:59 6 A. Yes.

15:53:00 7 Q. And in this instance you applied McGovern 10
15:53:04 8 using the Jensen time periods and found that the odds
15:53:09 9 ratio was 2.16; correct?

15:53:12 10 A. Something like that.

15:53:13 11 Q. Is that true?

15:53:15 12 A. I'd have to look it up.

15:53:31 13 Q. Page six.

15:53:46 14 A. "In this case the results are" blah, blah,
15 15 blah.

15:53:50 16 2.168. I'm sorry. Okay.

15:53:51 17 Q. Okay.

15:53:52 18 A. Yeah.

15:53:52 19 Q. So controlling for tinzaparin --

15:53:55 20 A. Yeah.

15:53:56 21 Q. -- in the Bair Hugger period compared to the
15:53:59 22 Hot Dog period, based on Albrecht 10, yielded an odds
15:54:03 23 ratio of 2.16; correct?

15:54:04 24 A. That's right.

15:54:05 25 Q. And the odds ratio that you calculated when

15:54:09 1 you used Albrecht 10, based on the uncontrolled

15:54:12 2 calculation, was 2.76; correct?

15:54:14 3 A. That's correct.

15:54:14 4 Q. The decrease in the odds ratio is .6;

15:54:17 5 correct?

15:54:17 6 A. That's right.

15:54:18 7 Q. So that would be at best the magnitude of
15:54:24 8 the degree of confounding if there is any confounding,
15:54:27 9 correct, based on your calculation?

15:54:29 10 A. Yeah. Well that -- that -- that change
15:54:32 11 would be a change due to controlling for --
15:54:42 12 controlling for use -- use of this -- of -- of this --
15:54:45 13 of this treatment, whatever that corresponds to.

15:54:48 14 Q. But I want to be clear that the change is .6
15:54:51 15 in the odds ratio; correct?

15:54:53 16 A. That's right. That's right.

15:54:55 17 Q. In your response to Mantel you say that the
15:54:58 18 inference on the disease factor association was quite
15:55:00 19 different when one controlled for age with respect to
15:55:04 20 cancer; correct?

15:55:06 21 A. It depended --

15:55:07 22 I don't know what the example was here.

15:55:09 23 Q. Okay. Would you --

15:55:11 24 A. Whatever it is.

15:55:12 25 Q. -- view a change of .6 to be quite

15:55:15 1 different?

15:55:15 2 A. I'd say it's a fair -- fair difference, yes.

15:55:19 3 Q. Okay.

15:55:19 4 A. So 2. -- 2.76, yeah, I mean that's --

15:55:23 5 it's --

15:55:27 6 Q. Approximately 20 percent.

15:55:29 7 A. Oh, it's more than 26 percent; isn't it?

15:55:32 8 It's --

15:55:37 9 Q. I don't think so.

15:55:40 10 A. -- two --

15:55:41 11 Q. .6 --

15:55:46 12 A. -- point --

15:55:48 13 Q. -- on 2.76?

15:55:49 14 A. Well the 2.76, that's a -- an increase of

15:55:52 15 1.76.

15:55:54 16 Q. From 2.76 to 2.16 is a difference of .6.

15:56:01 17 A. Right.

15:56:02 18 Q. Okay.

15:56:03 19 A. And so if there's no association, the odds

15:56:07 20 ratio is -- is -- is one.

15:56:11 21 Q. You're getting that from controlling both --

15:56:14 22 A. If there's no -- no association, you're

15:56:16 23 looking at --

15:56:17 24 Q. Correct.

15:56:18 25 A. -- the ratio of two incidence rates.

15:56:19 1 Q. This odds -- this odds ratio is still above

15:56:21 2 2.0 --

15:56:22 3 A. It is.

15:56:22 4 Q. -- when controlling for the

15:56:24 5 thromboprophylaxis; correct?

15:56:26 6 A. That's right.

15:56:27 7 Q. There is still a doubling of the risk even

15:56:29 8 when controlling for the thromboprophylaxis; correct?

15:56:33 9 A. That's right. So --

15:56:34 10 Q. Okay.

15:56:35 11 A. -- if you --

15:56:35 12 You're looking at a difference at -- at the

15:56:39 13 change above one, --

15:56:40 14 Q. Okay.

15:56:41 15 A. -- not -- not zero.

15:56:42 16 Q. But you would still agree that the --

15:56:45 17 A. It's a fairly big chart -- change.

15:56:48 18 Q. -- the change --

15:56:49 19 The controlled thromboprophylaxis OR is

15:56:52 20 still above 2.0.

15:56:53 21 A. It is, yes.

15:56:54 22 Q. And it --

15:56:55 23 That means it's still a doubling of the risk

15:56:57 24 even when the thrombo --

15:56:59 25 A. But the point -- the point estimate is

15:57:01 1 above. I mean look at the confidence limits.

15:57:03 2 Q. Of your calculation?

15:57:05 3 A. .7 --

15:57:05 4 After you control for it.

15:57:06 5 Q. Yes.

15:57:07 6 A. .73 to 8. --

15:57:10 7 I mean it's still --

15:57:11 8 Q. It's --

15:57:11 9 A. The estimate of what the effect is is not

15:57:14 10 very precise I would say.

15:57:15 11 Q. It's a third of the size of your Jensen

15:57:16 12 reanalysis; is it not? Your Jensen reanalysis has as

15:57:22 13 25-point confidence interval.

15:57:27 14 A. The 25, that's --

15:57:29 15 Q. One to 25.

15:57:31 16 MR. GORDON: Object to the form of the

15:57:32 17 question, assumes facts not in evidence.

15:57:35 18 A. Yeah. I -- you're looking at --

15:57:37 19 I mean those are not a fair comparison. I

15:57:41 20 mean --

15:57:42 21 Q. Why not?

15:57:45 22 A. I mean both of them are very poor estimates.

15:57:50 23 Q. Yours is three times the size --

15:57:53 24 A. Well you're looking at the range.

15:57:56 25 Q. -- of this.

15:57:56 1 A. Remember, I said, you know, the -- when you
15:57:58 2 construct a confidence interval on an odds ratio, you
15:58:01 3 generally do it on the log transformation, --

15:58:03 4 Q. Okay.

15:58:04 5 A. -- and so once you threw it -- do it in the
15:58:06 6 log, you have to look at it in the log scale.

15:58:09 7 Q. Okay. You would agree, nonetheless, that
15:58:12 8 the odds -- that the confidence interval you
15:58:15 9 calculated based on the Jensen reanalysis is larger
15:58:18 10 than the confidence interval of both the McGovern
15:58:20 11 study and the confidence interval that you report when
15:58:23 12 controlling for the thromboprophylaxis.

15:58:26 13 A. The range of the two would be greater, yes,
15:58:27 14 the range of the two would be greater, but a big part
15:58:30 15 of that reason for the change in the range, the
15:58:32 16 arithmetic difference in that range, is because the
15:58:36 17 odds ration is much smaller. In the other example in
15:58:40 18 the -- in the -- from the -- from the Jensen
15:58:43 19 comparison, the odds ratio was 4.77.

15:58:46 20 Q. Okay.

15:58:47 21 A. So that's more than twice --

15:58:50 22 Q. Okay.

15:58:52 23 A. -- what the odds ratio is here.

15:58:52 24 Q. Your odds ratio is more than three times the
15:58:55 25 ev -- the confidence interval here. Your confidence

15:58:59 1 interval is three times the size of the confidence
15:59:01 2 interval even though the odds ratio here is half the
15:59:03 3 amount of the odds ratio you reported --
4 A. Yes. Okay.
15:59:05 5 Q. -- in the Jensen reanalysis.
15:59:07 6 A. Okay.
15:59:08 7 Q. Okay.
15:59:09 8 A. So I don't -- I don't -- I don't understand
15:59:12 9 what your point is. But --
15:59:13 10 Q. My point is that it's clear that the Jensen
15:59:15 11 reanalysis has more variability than does your
15:59:18 12 calculation of the 2.16 odds ratio --
13 A. The difference between the high and low --
15:59:24 14 Q. -- when controlling for the
15:59:25 15 thromboprophylaxis; correct?
15:59:28 16 A. The difference be -- the -- the --
15:59:31 17 The difference between the high and the low
15:59:33 18 of the confidence interval is greater on that one
15:59:35 19 than -- is -- is diff -- quite different between those
15:59:40 20 two. I agree to that.
15:59:41 21 Q. It's greater.
15:59:42 22 A. It's greater. I agree with that.
15:59:45 23 Q. Thank you.
15:59:46 24 As to the Jensen reanalysis, have you
15:59:48 25 published your reanalysis of the Jensen study?

15:59:50 1 A. No.

15:59:51 2 Q. So you haven't reviewed any published
15:59:55 3 literature regarding the safety of Xarelto with
15:59:57 4 respect to deep joint infection.

16:00:00 5 MR. GORDON: Objection, asked and answered.

16:00:01 6 A. No, I've --

16:00:03 7 Q. Are you going to publish it?

16:00:05 8 A. No.

16:00:06 9 Q. So there is no published literature that you
16:00:09 10 are aware of that suggests a relationship between the
16:00:14 11 variable of a thromboprophylaxis on the outcome of
16:00:18 12 deep joint infection.

16:00:21 13 A. I don't know of any.

16:00:22 14 Q. Okay. If we could, let me show you another
16:00:28 15 document.

16:00:28 16 A. I mean it is interesting that they in
16:00:32 17 fact -- they seem to have not --

16:00:35 18 They went -- they went back to using the --
16:00:39 19 using the treatment they were originally using even
16:00:42 20 though the Jensen paper did not find it statistically
16:00:45 21 significant.

16:00:46 22 Q. You don't have an ex -- expertise in
16:00:47 23 infectious disease; do you?

16:00:50 24 A. No.

16:00:51 25 Q. You're not a medical doctor.

16:00:53 1 A. I'm not.

16:00:53 2 Q. You don't know why they changed back to
16:00:56 3 tinzaparin.

16:00:57 4 A. No, I -- no, I don't. I don't know if this
16:00:59 5 is the basis of it or not.

16:01:00 6 Q. Okay.

16:01:01 7 A. But I mean this was the ba --

16:01:02 8 It was Jensen's paper that -- that McGovern
16:01:06 9 is quoting, right, --

16:01:07 10 Q. Uh-huh.

16:01:08 11 A. -- as the -- as for saying why it's not a
16:01:12 12 confounder?

16:01:13 13 Q. And the Jensen --

16:01:14 14 A. And while the Jensen paper is not -- not
16:01:19 15 statistically significant, --

16 16 Q. Uh-huh.

16:01:21 17 A. -- they nevertheless changed the policy --
16:01:24 18 changed the regimen that they were using at Wansbeck.

16:01:27 19 Q. Okay. But you don't know why they did.

16:01:30 20 A. No, I don't.

16:01:30 21 Q. Okay.

16:01:31 22 A. I find it interesting.

16:01:43 23 Q. Did you ask anyone why they changed from
16:01:44 24 tinzaparin to Xarelto and back to tinzaparin?

16:01:47 25 A. No.

16:01:48 1 (Exhibit 27 was marked for
16:01:53 2 identification.)
16:01:53 3 BY MR. SACCHET:
16:01:54 4 Q. Did you ask 3M to investigate the issue?
16:01:58 5 A. Of why they changed back?
16:02:00 6 Q. Yes.
16:02:01 7 A. No.
16:02:01 8 Q. Okay. This is a section from Breslow and
16:02:09 9 Day; correct?
16:02:11 10 A. Is it? I don't -- I don't know. It
16:02:13 11 doesn't --
16:02:13 12 Oh, okay. Seems to be.
16:02:23 13 Q. And here on page 105 Breslow and Day state,
16:02:31 14 about in the middle of the page, paragraph begins "A
16:02:34 15 third way..." Do you see that?
16:02:35 16 A. Uh-huh.
16:02:36 17 Q. And the third sentence says, "Stratification
16:02:39 18 by factors which are not genuine confounding variables
16:02:42 19 would therefore increase the variability of the
16:02:44 20 estimates without eliminating any bias..." Do you
16:02:46 21 agree with that statement?
16:02:53 22 A. Trying to see what they're talking about
16:02:55 23 here.
16:02:59 24 MR. GORDON: I'm sorry, where are you?
16:03:00 25 MR. SACCHET: I'm on page 105 and the

16:03:03 1 paragraph starting "A third way...", in the third
16:03:06 2 par -- in the third sentence.

16:03:11 3 A. Okay. They're talking about overmatching.
16:03:14 4 Okay.

16:03:15 5 Q. Yes. Okay. And then they say, "It is
16:03:17 6 commonly seen when data are stratified by a variable
16:03:20 7 known to be associated with exposure but not in itself
16:03:24 8 independently related to disease;" correct?

16:03:26 9 A. Yes.

16:03:26 10 Q. So to the extent that you have a factor and
16:03:30 11 you control for that factor, even though it's related
16:03:34 12 to the -- even though it's related to the treatment
16:03:41 13 but not necessarily the outcome, that will result in
16:03:45 14 unnecessary bias; correct?

16:03:47 15 MR. GORDON: Object to the form of the
16:03:48 16 question.

16:03:51 17 A. I don't think the term they're using is
16:03:53 18 "bias," I think they're talking about variability.

16:03:56 19 Q. Okay. So --

16:03:56 20 A. That's different.

16:03:56 21 Q. Okay. You would agree to the extent that my
16:03:59 22 question involves variance or variability as opposed
16:04:04 23 to bias.

16:04:04 24 A. Okay.

16:04:04 25 Q. Okay.

16:04:04 1 A. So we're talking about vari -- variance and
16:04:06 2 not bias. Okay.

16:04:07 3 Q. Okay. So in the event that, for the sake of
16:04:12 4 argument, the thromboprophylaxis is not in fact
16:04:16 5 related to the outcome of interest, which is deep
16:04:19 6 joint infection, if one were to control for the
16:04:22 7 thromboprophylaxis, that would inject variance;
16:04:26 8 correct?

16:04:26 9 MR. GORDON: Object to the form of the
16:04:27 10 question, assumes facts not in evidence, incomplete
16:04:30 11 hypothetical.

16:04:33 12 A. I mean I think what you see -- what --
16:04:36 13 What this is saying, if it's not, then they
16:04:41 14 would -- it would have no effect on the estimate but
16:04:44 15 it would increase the variance.

16:04:46 16 Q. Okay.

16:04:47 17 A. Okay?

16:04:48 18 Q. Yeah.

16:04:49 19 A. In the control that -- that I did in this
16:04:57 20 analysis, the estimate did change.

16:05:01 21 Q. And the confidence interval did, too;
16:05:03 22 correct?

16:05:03 23 A. And confidence --

16:05:05 24 They both changed, yes.

16:05:06 25 Q. And that confidence interval measures

16:05:08 1 variance.

16:05:09 2 A. That's -- that's an indication of precision.

16:05:10 3 Q. Okay.

16:05:11 4 A. Yeah.

16:05:11 5 Q. If we look at --

16:05:12 6 A. And so what they're saying here is that

16:05:14 7 you've -- you've got a variable, there's no point in

16:05:17 8 controlling it. To control for bias, it's not going

16:05:23 9 to do anything to that, --

16:05:24 10 Q. Okay.

16:05:25 11 A. -- and so you're just throwing it in there

16:05:28 12 unnecessarily and that's going to increase the

16:05:29 13 variance.

16:05:29 14 Q. Okay.

16:05:30 15 A. And so -- so I would -- I would agree with

16:05:34 16 that, but I would disagree that that corresponds to

16:05:39 17 that particular analysis on page six --

16:05:42 18 Q. In --

16:05:43 19 A. -- of my report.

16:05:44 20 Q. -- the bottom paragraph, the last full

16:05:47 21 sentence states, "Good evidence may be available from

16:05:50 22 previous studies that C is not causally related to

16:05:54 23 disease, in which case it should not be incorporated

16:05:57 24 as a confounder." Do you see that?

16:06:01 25 A. Yes.

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16:06:04 1 Q. Are you aware that the record studies found
16:06:09 2 that Xarelto is not related to infection?

16:06:14 3 MR. GORDON: Objection, asked and answered,
16:06:16 4 lack of foundation.

16:06:19 5 A. I think I said I had not looked at the
16:06:22 6 record studies.

16:06:23 7 Q. Would it be helpful to look at one?

16:06:26 8 A. I mean I -- it --

16:06:32 9 When I was looking within the Albright 10
16:06:36 10 data set, I found the association that I reported.
16:06:41 11 Now I think the premise of your question is: Is the
16:06:48 12 association that I found, is that a causal association
16:06:51 13 or not? The way this study was designed, is this
16:06:58 14 temporal? You know, these time periods are changing.
16:07:06 15 And as I show in Fig. 2 --

16:07:15 16 Q. Okay.

16:07:16 17 A. -- show in Fig. 2 and I present the --
16:07:20 18 related to that I show in figure -- I'm sorry, on
16:07:31 19 page -- ah, where is that? On page four, the last
16:07:43 20 paragraph, it compares the infection rates by
16:07:49 21 quarter --

16:07:49 22 Q. Yeah.

16:07:50 23 A. -- and we got a chi-square of 15.5 on six
16:07:54 24 degrees of freedom, p-value of .0167. So what that
16:07:59 25 suggests is that the incidence rates during the Bair

16:08:05 1 Hugger period were changing quite a lot, and those
16:08:11 2 differences were statistically significant.

16:08:13 3 Q. Okay.

16:08:14 4 A. So this is not a period where things were
16:08:17 5 just under well controlled.

16:08:21 6 Q. Are you aware of whether deep joint
16:08:23 7 infections are always constant or whether there is
16:08:25 8 variability in deep joint infections more generally?

16:08:28 9 A. Well if there is variability more generally,
16:08:30 10 then that needs to be taken into account in the
16:08:32 11 analysis, and this analysis does not do that.

16:08:35 12 Q. When you conducted --

16:08:37 13 A. I did not do that, and McGovern certainly
16:08:38 14 didn't do it either.

16:08:39 15 Q. When you construct a statistical model, the
16:08:41 16 confidence interval accounts for the variance of the
16:08:44 17 data; correct?

16:08:44 18 A. Well it should. But the confidence
16:08:49 19 intervals that I computed and the confidence intervals
16:08:52 20 that McGovern computed don't take that -- that
16:08:57 21 variability into account.

16:08:57 22 Q. Okay.

16:08:59 23 A. The expected value of this chi-square
16:09:01 24 statistic is equal to the degrees of freedom, so you
16:09:03 25 expect it to be six, in fact it's 15.5, so there's,

16:09:08 1 what, two and a half times as much variability as what
16:09:12 2 I would expect to see if the only variation that was
16:09:15 3 taking place was just a random fluctuation based on,
16:09:20 4 you know, what's going on with the use of -- of -- of
16:09:24 5 these surgical procedures at Wansbeck.

16:09:27 6 Q. You didn't do that calculation with respect
16:09:29 7 to the reanalysis of the Jensen data; correct?

16:09:34 8 A. I -- I didn't -- I didn't allow for random
16:09:38 9 variability other than the binomial variability --

10 Q. Okay.

16:09:45 11 A. -- that -- that we assumed. No, I -- I took
16:09:47 12 that at a face value. And -- and it could be random.
16:09:52 13 My assumption is it's not random. My assumption is
16:09:55 14 it's due to other factors that are -- that were
16:10:00 15 affecting risk at Wansbeck during this time period.

16:10:03 16 Q. That's an assumption.

16:10:04 17 A. It is.

16:10:05 18 Q. Okay. I want to go back to the -- what we
16:10:09 19 were talking about with respect --

16:10:15 20 Did you do any investigation to determine
16:10:18 21 whether your assumption was correct or not?

16:10:22 22 A. I -- I have no further --

16:10:24 23 I have not been in contact with Wansbeck or
16:10:26 24 anyone else involved with this to know that for
16:10:29 25 certain. I guess a part of my -- my -- my reasons for

16:10:32 1 thinking there were other things going on is the
16:10:36 2 Gillson paper, for example, enumerates such a huge
16:10:43 3 array of things that were taking place at -- what is
16:10:48 4 it -- Northumbria group of hospitals, --

16:10:51 5 Q. Okay.

16:10:52 6 A. -- so they were having a problem.

16:10:54 7 Obviously, NHS was -- was calling them on having a
16:11:00 8 high infection rate that they needed to do something
16:11:04 9 about, and the -- the Gissell paper elaborates on all
16:11:09 10 the things that they were trying to do to bring this
16:11:11 11 thing under control, and there were a lot of other
16:11:13 12 things other than switching to Hot Dog.

16:11:16 13 Q. Okay. Did you ask 3M for any info with
16:11:19 14 respect to this issue?

16:11:19 15 A. No.

16:11:20 16 MR. GORDON: Object to the form of the
16:11:21 17 question.

16:11:21 18 Q. Okay. Are you aware that in the Gillson
16:11:23 19 article the descriptor for infection is SSI?

16:11:28 20 MR. GORDON: Object to the form of the
16:11:29 21 question.

16:11:29 22 Q. The title of the article is SSI.

16:11:33 23 A. Which paper are you talking about?

16:11:35 24 Q. You just referenced the Gillson article, --

16:11:37 25 A. Gillson, okay.

16:11:38 1 Q. -- "Implementing Effective SSI Measures."

16:11:41 2 A. Right. Yes.

16:11:42 3 Q. Do you know what "SSI" stands for?

16:11:45 4 A. Ahh, oh --

16:11:49 5 I've forgotten.

16:11:50 6 Q. Surgical-site infection ring a bell?

16:11:52 7 A. Surgical-site infection. Exactly, yeah.

16:11:54 8 Q. Surgical-site infections are not the same
16:11:57 9 thing as deep joint infections.

16:11:57 10 MR. GORDON: Object to the form of the
16:11:58 11 question, lack of foundation, misconstrues the
16:12:01 12 evidence and assumes facts not in evidence.

16:12:03 13 Q. Do you know whether an SSI is the same as a
16:12:05 14 DJI?

16:12:06 15 MR. GORDON: Same objection.

16:12:08 16 A. It's -- it's not the same, it's not the same
16:12:11 17 thing. They are -- they would be --

16:12:13 18 Are you saying -- suggesting they are not
16:12:14 19 related?

16:12:15 20 Q. I'm suggesting that --

16:12:17 21 Do you know whether the measures that were
16:12:18 22 implemented in the Northumbria trust were specific to
16:12:23 23 SSI or DJI?

16:12:27 24 A. I think --

16:12:28 25 Well the paper is entitled for SSI.

16:12:31 1 Q. So you don't know whether they were specific
16:12:33 2 to deep joint infection.

16:12:33 3 A. Well I would assume that they would -- they
16:12:36 4 would be effective on affecting both. I mean
16:12:42 5 orthopedic surgery appears to be one of the things
16:12:44 6 that they are in fact looking at.

16:12:46 7 Q. Can you define SSI?

16:12:49 8 A. I don't know the --

16:12:51 9 I don't know. I'm -- it's not a -- an area
16:12:53 10 that I've particularly done -- done work -- work on.
16:12:57 11 I --

16:12:57 12 Q. Can you define DJI?

16:12:59 13 A. It's -- it's again the --

16:13:03 14 It's joint -- joint infections --

15 Q. Okay.

16:13:07 16 A. -- that -- that you're looking at.

16:13:08 17 Q. But you have no scientific basis or
16:13:11 18 expertise to conclude whether or not the inter --
16:13:14 19 interventions that are mentioned in the Gillson
16:13:16 20 article which relate to SSI would have an impact on
16:13:20 21 deep joint infection; correct?

16:13:21 22 A. It's --

16:13:22 23 They're not areas that I have -- that I
16:13:25 24 have -- that I have personally done research on.

16:13:28 25 My -- my --

16:13:29 1 But I -- I believe that they would be
16:13:33 2 related to each other. And things that you're doing
16:13:35 3 to control SSI, my understanding is you would have --
16:13:46 4 you would have effects on -- on PJI as well.

16:13:52 5 Q. What's your understanding based on?

16:13:56 6 A. Well looking at -- well I mean the -- one --
16:14:00 7 This is from the -- from the Gillson paper.

16:14:07 8 Q. What is?

16:14:08 9 A. A patient with a -- with a -- with surgery
16:14:12 10 on his knee.

16:14:13 11 Q. Do you see the implant?

16:14:14 12 A. I see the surgery on his knee.

16:14:16 13 Q. Do you know whether that would result in
16:14:18 14 either a superficial wound infection on the skin or
16:14:20 15 whether it would result in a deep infection on a
16:14:24 16 prosthetic?

16:14:24 17 A. I don't know. If it was a deep infection, I
16:14:26 18 think that would be something they would -- they would
16:14:28 19 be interested in.

16:14:29 20 You don't think that -- you don't think they
16:14:31 21 would be interested in that as -- as respect to the
16:14:35 22 surgery?

16:14:35 23 Q. Are you asking me?

16:14:37 24 A. Yeah.

16:14:37 25 Q. I'm --

16:14:38 1 A. I mean you -- you seem to be suggesting that
16:14:40 2 there's no effect. Why -- why what you're asking
16:14:43 3 me --

16:14:45 4 Q. I would let --
16:14:45 5 Your -- your report concludes that the SSI
16:14:46 6 bundle may have had an effect on deep joint infection
16:14:49 7 rates; correct?

16:14:51 8 A. Yes. The things that they were doing to
16:14:54 9 control SSI may have had an effect.

16:14:56 10 Q. You have no scientific basis to make that
16:14:59 11 conclusion.

16:15:01 12 A. I'm -- no, no. I'm just -- just assuming
16:15:04 13 that it does.

16:15:04 14 Q. Thank you.

16:15:06 15 Do you know if any articles that you're
16:15:09 16 relying on relate to SSI versus DJI?

16:15:14 17 A. No.

16:15:15 18 Q. So you're not sure whether the publications
16:15:17 19 that you've cited on page 14 of your report are
16:15:20 20 specific to deep joint infection or a surgical-site
16:15:26 21 infection.

16:15:26 22 A. Oh. Some of them --

16:15:34 23 I'm not sure which articles you're -- you're
16:15:38 24 talking about.

16:15:39 25 Q. Well do you know offhand? I don't want to

16:15:41 1 spend a ton of time on this.

16:15:44 2 A. I don't -- I don't know offhand.

16:15:45 3 Q. Okay.

16:15:46 4 A. I --

16:16:12 5 Q. With respect to the conclusions that you've

16:16:14 6 offered in your report, did you distinguish between

16:16:17 7 SSI and DJI?

16:16:24 8 A. I don't know that you're --

16:16:26 9 Most of what I was talking about in the

16:16:28 10 report has to do with analysis of -- of -- of

16:16:35 11 McGovern.

16:16:36 12 Q. Do you know whether Albrecht 10, for

16:16:38 13 example, contained data on SSI versus DJI?

16:16:45 14 A. I don't recall that it -- it did. I think

16:16:48 15 it was basically looking at the -- the internal

16:16:54 16 infections.

16:16:55 17 Q. But you don't know whether those infections

16:16:57 18 were SSI or DJI.

16:17:00 19 A. I --

16:17:01 20 MR. GORDON: Object to the form of the

16:17:02 21 question.

16:17:02 22 A. I wasn't --

16:17:04 23 They were looking at in -- in -- whatever

16:17:06 24 their definition was of -- of infection.

16:17:09 25 Q. But you don't know what that is.

16:17:11 1 A. They de --

16:17:13 2 I don't re -- recall exactly what the detail
16:17:14 3 is there. They defined it in -- it's defined in
16:17:18 4 McGovern, and it's identified as one of the variables
16:17:22 5 that is in Albrecht -- Albrecht 10.

16:17:24 6 Q. Albrecht 10 says what they're defined as,
16:17:27 7 whether they are DJI or SSI?

16:17:30 8 A. I don't recall if it said that. It just
16:17:32 9 said a --

16:17:35 10 Q. I'll represent to you that it doesn't.

16:17:38 11 A. Okay.

16:17:39 12 Q. So you're not sure one way or the other
16:17:42 13 whether the data in Albrecht Exhibit 10 is specific to
16:17:45 14 SSI versus DJI, considering that the Gillson article
16:17:49 15 is talking about SSI.

16:17:53 16 MR. GORDON: Object to the form of the
16:17:54 17 question, assumes facts not in evidence.

16:17:57 18 A. I was using the definition that -- that was
16:18:00 19 in Albrecht 10.

16:18:01 20 Q. Where is the definition in Albrecht 10?

16:18:03 21 A. Well they defined it to -- to define their
16:18:10 22 variable that indicated --

16:18:12 23 What was the variable called?

16:18:16 24 Q. It's not in there; is it, professor?

16:18:19 25 A. Well there's one of the -- it's one of these

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16:18:22 1 columns. They are -- they are labeled, and somewhere
16:18:29 2 in here --

16:18:36 3 I've forgotten the variable names that they
16:18:39 4 used.

16:18:54 5 Q. Do you see it?

16:19:00 6 A. Deep infection.

16:19:01 7 Q. Do you know whether that's DJI or SSI?

16:19:04 8 A. I don't know.

16:19:04 9 Q. Okay. Do you know whether --

16:19:10 10 A. Well DJ -- I think it's DJ -- DJI, that DJI
16:19:17 11 is deep joint infection.

16:19:18 12 Q. Do you know whether the mechanism of
16:19:19 13 infection differs between the DJI and SSI?

16:19:23 14 A. No.

16:19:24 15 Q. Okay. I'd like to turn back to the Breslow
16:19:35 16 and Day article that we were looking at, which has
16:19:36 17 been marked as Exhibit 26 I believe.

16:19:42 18 THE REPORTER: Before we do that, let's go
16:19:44 19 off the record, take five minutes.

16:19:54 20 (Recess taken.)

16:30:02 21 BY MR. SACCHET:

16:30:06 22 Q. Professor Holford, you have also analyzed
16:30:09 23 the change in the antibiotic regime that occurred
16:30:13 24 during the McGovern study; correct?

16:30:14 25 A. Yes.

16:30:15 1 Q. And there was a change from Gentamicin to
16:30:19 2 Gentamicin plus Teicoplanin; correct?

16:30:23 3 A. That's correct.

16:30:23 4 Q. And the change happened at the tail end of
16:30:25 5 the Bair Hugger period with some time left, and then
16:30:28 6 it was fully in force during the Hot Dog period;
16:30:32 7 correct?

16:30:32 8 A. Yeah.

16:30:32 9 MR. GORDON: Well I'll object to the form of
16:30:34 10 the question.

16:30:37 11 Q. Are you aware of the relationship between
16:30:40 12 using prophylactic antibiotics on DJI versus SSI?

16:30:46 13 MR. GORDON: Object to the form of the
16:30:47 14 question, lack of foundation.

16:30:49 15 A. I'm not familiar with that, no.

16:30:51 16 Q. Did you conduct any research to determine
16:30:52 17 how antibiotics operate as to the outcome of DJI
16:30:56 18 versus SSI?

16:30:57 19 A. No.

16:30:58 20 Q. Did you ask 3M for any information about how
16:31:02 21 change from Gentamicin to Gentamicin plus Teicoplanin
16:31:06 22 might affect deep joint infection rates?

16:31:08 23 A. No.

16:31:09 24 Q. Do you have any knowledge of how Gentamicin
16:31:12 25 versus Gentamicin and Teicoplanin affects joint

16:31:17 1 infection rates?

16:31:18 2 A. Other than the -- the analysis that I did
16:31:20 3 using Albrecht 10, that -- that's basically what I was
16:31:24 4 using.

16:31:25 5 Q. In your report you assume that the
16:31:27 6 thromboprophylaxis may be a confounding factor, but
16:31:31 7 you never state as much with respect to the
16:31:34 8 antibiotic; is that true?

16:31:36 9 A. I don't know if I stated it. It is -- it is
16:31:38 10 potentially a -- a -- a confounding variable and in
16:31:43 11 fact I did adjust for it in -- I did present an
16:31:47 12 analysis where I adjusted for it.

16:31:49 13 Q. So did you adjust for the antibiotic without
16:31:53 14 considering whether it was a confounding factor?

16:31:56 15 A. Well, I mean whether it's a confounding
16:32:01 16 factor, as I -- as I said before, it -- it depends on
16:32:06 17 whether -- whether there is a change in the --

16:32:11 18 It affects the -- the association.

16:32:14 19 Q. Okay.

16:32:15 20 A. And in this case the association -- let's
16:32:22 21 see.

16:32:24 22 When we just controlled for the
16:32:36 23 thromboprophylaxis --

16:32:38 24 Q. I think we're on the antibiotic.

16:32:41 25 A. Yes. When we just controlled for -- for

16:32:44 1 the -- for the thromboprophylaxis, the -- the odds
16:32:49 2 ratio was, what, 2.49? Is that right? No, I'm sorry,
16:33:01 3 2.16.

16:33:08 4 Q. That's the odds ratio for controlling for
16:33:10 5 the thromboprophylaxis; correct?

16:33:12 6 A. From -- from --

16:33:13 7 Yes, right.

16:33:13 8 Q. And we're talking about the antibiotic.

16:33:16 9 A. And then so now when we add, in addition to
16:33:18 10 controlling for the thromboprophylaxis we're adding
16:33:21 11 the antibiotic, which is what you were asking about --

16:33:24 12 Q. Well I actually wasn't asking about that.
16:33:26 13 I'm asking for just with respect to the antibiotic,
16:33:28 14 not controlling for both, just controlling for the
16:33:31 15 antibiotic. You did that calculation prior to the
16:33:33 16 double control; correct?

16:33:35 17 A. I don't know that I did the single control.

16:33:37 18 Q. Okay.

16:33:37 19 A. I looked -- I looked --

16:33:39 20 I did a double control.

16:33:40 21 Q. You don't recall doing a single control on
16:33:48 22 the antibiotic?

16:33:50 23 A. I don't think I did.

16:33:54 24 Q. Well you did.

16:33:55 25 A. Oh, I did? Okay.

16:33:57 1 MR. GORDON: On page six.

16:33:58 2 Q. It's on page six.

16:34:00 3 A. Oh, I'm sorry.

16:34:01 4 Q. Right under the heading "Comparison of the
16:34:03 5 effect of antibiotic regimen on study results." And
16:34:08 6 you report that there was a rate of infection during
16:34:12 7 the Bair Hugger period when Gentamicin was used of
16:34:16 8 1.92 percent; correct?

16:34:17 9 A. Oh, okay. This is --

16:34:21 10 Yeah. We were -- I think we were talking
16:34:22 11 about two different things. This is, I think, just
16:34:25 12 looking at the effect of an antibiotic on --

16:34:28 13 Q. Yes.

14 A. Yeah.

16:34:30 15 Q. Okay.

16:34:30 16 A. I was talking about controlling for it.

16:34:31 17 Yeah.

16:34:31 18 Q. Okay. So here we essentially controlled for
16:34:34 19 the use of the Bair Hugger and viewed infection rates
16:34:39 20 when Gentamicin was applied versus when Gentamicin
16:34:42 21 plus Teicoplanin was applied; correct?

16:34:44 22 A. That's right. Because it's only during
23 the --

24 Q. Yeah.

16:34:46 25 A. -- Bair Hugger.

16:34:46 1 Q. Yeah.

16:34:46 2 A. Sure.

16:34:47 3 Q. And protocol one, which we'll call the
16:34:50 4 Gentamicin administration, resulted in an infection
16:34:52 5 rate of 1.92 percent in patients; correct?

16:34:57 6 A. Yes.

16:34:58 7 Q. Okay. And then protocol two, when
16:35:01 8 Gentamicin plus Teicoplanin was used, the rate went up
16:35:05 9 to 3.13; correct?

16:35:06 10 A. That's right.

16:35:07 11 Q. That's an increase in the infection rate;
16:35:09 12 correct?

16:35:09 13 A. Yes.

16:35:09 14 Q. And that's the combination of antibiotics
16:35:13 15 that was used during the Hot Dog period; correct?

16:35:15 16 A. Yes.

16:35:16 17 Q. So actually, the combination of antibiotics
16:35:18 18 that was used resulted in a higher infection rate
16:35:23 19 between -- compared to the drug that was used with
16:35:24 20 just Bair Hugger patients; correct?

16:35:25 21 A. That's right.

16:35:29 22 Q. So if anything --

16:35:30 23 A. Yeah. It's the com -- wait.

16:35:44 24 That's right. Yeah.

16:35:45 25 Q. Okay.

16:35:45 1 A. The switchover. Okay. Sorry.

16:35:47 2 Q. So if anything, there's actually reverse
16:35:50 3 confounding in the direction that the use of
16:35:52 4 Gentamicin plus Teicoplanin was less effective than
16:35:56 5 the use of just Gentamicin; correct?

16:36:00 6 A. It appears to be, yes.

16:36:02 7 Q. So based on that conclusion, the odds ratio
16:36:06 8 as reported in the McGovern study could even be higher
16:36:09 9 in the event that we controlled for the use of
16:36:13 10 Gentamicin plus Teicoplanin; correct?

16:36:17 11 A. Well --

16:36:17 12 Q. You just told me statistical significance
16:36:20 13 did not matter.

16:36:21 14 MR. GORDON: Object to the form of the
16:36:22 15 question, misstates his testimony.

16:36:25 16 A. I mean the issue of it being a confounder is
16:36:28 17 does it affect the association -- does it affect the
16:36:31 18 measure of association between -- the --

16:36:47 19 Well, in this case we're looking at Bair
16:36:49 20 Hugger, Bair Hugger/Hot Dog, does it -- does it affect
16:36:51 21 that association.

16:36:52 22 Q. You didn't report an association; did you?

16:36:56 23 MR. GORDON: Object to the form of the
16:36:57 24 question.

16:36:58 25 A. Yeah, it --

16:36:59 1 Q. Did you report an association with respect
16:37:00 2 to controlling for the antibiotic in the Bair Hugger
16:37:04 3 arm of the study?

16:37:06 4 MR. GORDON: Just the antibiotic?

16:37:08 5 MR. SACCHET: Yeah.

16:37:09 6 A. Not just the antibiotic, no. That's what I
16:37:12 7 said, I didn't do that.

16:37:14 8 Q. You didn't do that.

16:37:15 9 A. Look at the effect of --

16:37:19 10 Well I -- I looked at the effect of -- of
16:37:26 11 the antibiotic --

16:37:27 12 Q. Yeah.

16:37:27 13 A. -- on risk of infection, --

16:37:35 14 Q. Okay.

16:37:35 15 A. -- and that was this difference of, oh, 1.9
16:37:39 16 versus 3.1 infection rate with a p-value of .17.

16:37:45 17 Q. Okay. And the percent of infection when
16:37:48 18 using Gentamicin plus Teicoplanin went up compared to
16:37:52 19 the use of just Gentamicin; correct?

16:37:56 20 A. That's right.

16:37:57 21 Q. And in the McGovern study, all the Hot Dog
16:38:00 22 patients received Gentamicin plus Teicoplanin;
16:38:04 23 correct?

16:38:04 24 A. Yeah.

16:38:04 25 Q. This calculation that you performed shows

16:38:07 1 that Gentamicin may be less effective than Gentamicin

16:38:13 2 plus Teicoplanin; correct?

16:38:14 3 A. It -- it --

16:38:15 4 The point estimates go in that direction.

16:38:17 5 It's not --

6 Q. Okay.

16:38:18 7 A. -- statistically significant, --

16:38:19 8 Q. Okay.

16:38:19 9 A. -- although it's --

16:38:21 10 It's sort of unclear as to whether or not it

16:38:23 11 does.

16:38:23 12 Q. With respect to confounding, you previously

16:38:25 13 stated that statistical significance is not

16:38:27 14 determinant of whether there is confounding; correct?

16:38:30 15 A. That's right.

16:38:30 16 Q. So whether or not the p-value is .1683 does

16:38:34 17 not mean that there was reverse confounding with

16:38:38 18 respect to the odds ratio reported in the McGovern

16:38:41 19 study; correct?

16:38:42 20 A. It's -- it --

16:38:44 21 Well it basically means that it's -- it's --

16:38:46 22 it's -- it could go either way.

16:38:49 23 Q. It could --

16:38:50 24 A. It's not -- it's not clear.

16:38:51 25 Q. Okay. And you have not reported an odds

16:38:54 1 ratio with respect to that calculation; correct?

16:38:57 2 A. No, it does --

16:38:58 3 No, I have not.

16:38:59 4 Q. So in order to determine whether there was
16:39:01 5 reverse confounding or general confounding, you have
16:39:04 6 not made the calculation in order to make that
16:39:07 7 conclusion; correct?

16:39:08 8 A. I haven't said whether or not it's reverse
16:39:11 9 or --

16:39:11 10 I'm not -- I'm not sure what -- what you
16:39:13 11 mean by "reverse" or --

16:39:14 12 Q. That's what I said, "whether or not." You
16:39:18 13 don't know whether there was confounding because you
16:39:20 14 haven't reported an odds risk ratio with respect to
16:39:21 15 just the control for the antibiotic; correct?

16:39:24 16 A. Well it's not just control. I've -- I've
16:39:26 17 controlled for both antibiotic and thrombo.

16:39:29 18 Q. I understand. But with respect to
16:39:31 19 controlling for the antibiotic in this calculation --

16:39:33 20 A. Yes.

16:39:33 21 Q. -- you report infection rates and you report
16:39:35 22 a p-value, you do not report an odds ratio; correct?

16:39:38 23 A. That's correct.

16:39:39 24 Q. There is no way to determine whether the
16:39:41 25 odds ratio increased compared to what was provided in

16:39:44 1 the McGovern study or whether it decreased,
16:39:46 2 correct, --
16:39:47 3 A. Which odds --
4 Q. -- when com --
16:39:48 5 A. -- ratio are you talking about?
16:39:49 6 Q. Either the 3.8 or the 2.76 that you
16:39:52 7 calculated based on Albrecht 10. You have no basis to
16:39:55 8 compare those odds ratios to this calculation.
16:39:59 9 A. Well I compared the odds -- I mean I
16:40:02 10 didn't --
16:40:02 11 I don't report the odds ratio, but you can
16:40:04 12 pretty good -- get a pretty good idea of what -- about
16:40:07 13 what it's going to be --
16:40:08 14 Q. You told me --
16:40:09 15 A. -- because the infection rate -- let's see.
16:40:15 16 "In order to control for the...one must use
16:40:18 17 the Bair Hugger period that -- that shares the
16:40:21 18 antibiotic and thromboprophylaxis regimen used in the
16:40:25 19 Hot Dog period," so -- which had an infection rate of
16:40:31 20 three out of 270, 1.1 percent, and compare that with
16:40:36 21 four out of 372, which is 1.08 percent.
16:40:41 22 Q. You're looking at controlling for both
16:40:42 23 variables, correct, right now?
16:40:44 24 A. That is correct.
16:40:44 25 Q. I want to go back to when you just

16:40:46 1 controlled for the antibiotic, which is what we're
16:40:48 2 talking about. You did not provide an odds ratio.

16:40:50 3 A. I did not --

16:40:51 4 That's right, I didn't provide it.

16:40:52 5 Q. You did not determine how or whether the
16:40:55 6 antibiotic by itself is a confounding variable.

16:40:58 7 A. By -- by itself, no. By itself, no.

16:41:00 8 Q. And you have --

16:41:01 9 A. But I've controlled for both of them --

16:41:04 10 Q. We'll get there. I'm just talking about
16:41:05 11 this calculation.

16:41:05 12 You do not know the degree of confounding,
16:41:08 13 if any, caused by only the antibiotic.

16:41:10 14 A. That's right. I didn't do that.

16:41:12 15 Q. And you have not reviewed any literature to
16:41:14 16 suggest that an antibiotic is a confounding factor on
16:41:19 17 deep joint infections.

16:41:20 18 MR. GORDON: Object to the form of the
16:41:22 19 question.

16:41:22 20 A. I don't see -- understand that -- understand
16:41:27 21 your -- your question. To be a confounding variable,
16:41:30 22 as we've said, it has to be associated with -- with
16:41:36 23 the -- with the outcome --

16:41:37 24 Q. Okay.

16:41:38 25 A. -- and the variable you're looking at.

16:41:41 1 Q. Yeah. And you haven't done --

16:41:42 2 A. So whether or not it's associated with --

16:41:44 3 Well in this study it -- it certainly is
16:41:47 4 associated with -- with whether or not the Bair Hugger
16:41:50 5 or the Hot Dog was used. In general, who knows?

16:41:57 6 Q. You don't know whether --

16:41:59 7 A. Well --

16:42:00 8 Q. -- the Gentamic --

16:42:02 9 A. -- it depends on what -- what -- what is
16:42:03 10 done by the institution.

16:42:05 11 Q. You don't know whether Gentamicin is more or
16:42:07 12 less effective than Gentamicin plus Teicoplanin --

16:42:09 13 A. Well that's a different question.

16:42:11 14 Q. -- in terms of deep joint infection. That's
16:42:12 15 the question right now. Do you know?

16:42:19 16 A. Well there is the --

16:42:22 17 The analysis based on these data --

16:42:25 18 Q. That shows --

16:42:26 19 A. -- found -- found the -- the result was not
16:42:28 20 statistically significant, the difference of 2.19
16:42:32 21 percent versus 3.1, but -- but --

16:42:33 22 Q. And the infection rate went up with
16:42:36 23 Gentamicin plus Teicoplanin.

16:42:38 24 A. That's right.

16:42:39 25 Q. Okay.

16:42:39 1 A. The one -- the one is higher. It's not --

16:42:41 2 That difference is not statistically

16:42:42 3 significant.

16:42:43 4 Q. Okay. Based on that --

16:42:44 5 A. When I -- when I added that into the

16:42:46 6 analysis and controlled for that after I had already

16:42:50 7 controlled from thromboprophylaxis, the -- any

16:42:53 8 association that -- an association that was 2.1 --

16:42:57 9 six was it? -- com -- disappeared effectively

16:43:01 10 completely, I mean 1 -- 1. -- 1.11 percent versus

16:43:07 11 1.08.

16:43:07 12 Q. Okay. Let's talk about --

16:43:08 13 A. So they're basically -- I mean it -- as --

16:43:12 14 It would, I -- I -- I suggest, be an

16:43:15 15 indication that this is a confounding variable because

16:43:19 16 the odds ratio is bas -- basically eliminated.

16:43:23 17 Q. Have you done a powering analysis of this

16:43:25 18 double-control calculation?

16:43:26 19 A. A power analysis, no.

16:43:27 20 Q. You have no idea whether this is adequately

16:43:30 21 powered.

16:43:30 22 A. Oh, it's -- I -- there's --

16:43:32 23 There's never been a power analysis of

16:43:34 24 anything related to McGovern.

16:43:35 25 Q. You don't know whether this calculation --

16:43:37 1 A. I don't -- I mean why are --

16:43:39 2 What is the issue? The power to do what? I

16:43:42 3 don't know what you're asking.

16:43:43 4 Q. You're analyzing a population of 270 persons

16:43:49 5 and 372 persons, totaling approximately 600 people;

16:43:55 6 correct?

16:43:55 7 A. So what's your -- what's your hypothesis?

16:43:58 8 Q. My question is: If the McGovern study was,

16:44:00 9 in your words, a relatively small population based on

16:44:03 10 the incidence of infection and was therefore

16:44:05 11 unreliable, --

16:44:06 12 A. Yeah.

16:44:07 13 Q. -- you've cut the population in half.

16:44:09 14 A. Okay.

16:44:09 15 Q. Doubly unreliable.

16:44:11 16 A. Well whether it's double or not, I -- it's

16:44:14 17 not -- it's un -- it's unclear.

16:44:16 18 Q. More unreliable.

16:44:17 19 A. It -- it will be more -- more -- it will

16:44:19 20 have less --

16:44:20 21 The study would have -- would have even less

16:44:22 22 power, that's true.

16:44:23 23 Q. More unreliable.

16:44:26 24 A. What do you mean by "reliable?"

16:44:28 25 Q. More variance.

16:44:28 1 A. More variance, yes.

16:44:33 2 Q. If anything, the best way to figure out
16:44:36 3 whether the thromboprophylaxis and the antibiotic
16:44:41 4 confounded the results in a population of patients who
16:44:45 5 were subjected to Bair Hugger warming versus Hot Dog
16:44:48 6 warming would be to look at a larger sample size when
16:44:50 7 both of those variables are controlled; correct?

16:44:53 8 A. Well one would have to look at what the --
16:45:02 9 What I think is needed is a proper
16:45:05 10 protocol --

16:45:05 11 Q. Okay.

16:45:06 12 A. -- which would address the issue of power,
16:45:09 13 and you would have to specify what magnitude of effect
16:45:12 14 you wanted -- wanted to detect, --

16:45:13 15 Q. Okay.

16:45:14 16 A. -- and this, as far as I can tell, was never
16:45:18 17 done by this group.

16:45:19 18 Q. Okay. I'm going to ask the question again
16:45:22 19 because that didn't respond to it.

16:45:23 20 A better analysis than what you have done
16:45:26 21 here with respect to controlling for both var --
16:45:29 22 variables would be to look at a larger population of
16:45:33 23 patients who received the same thromboprophylaxis and
16:45:37 24 the same antibiotic; correct?

16:45:44 25 A. Well --

16:45:47 1 Q. There would be less variance.

16:45:49 2 A. Oh, if you -- if you -- if you restricted
16:45:53 3 both of those, but I mean that's not your only option.
16:45:56 4 If you restricted it to those groups and had an
16:45:59 5 increased sample size, that would -- that would
16:46:01 6 certainly give you more power.

16:46:02 7 Q. Yeah. It would -- it would be a more
16:46:04 8 accurate representation of whether those two variables
16:46:06 9 were confounders or not; correct?

16:46:09 10 A. If that's what you were interested in.

16:46:10 11 Q. Okay. It would be a more accurate
16:46:13 12 representation as to whether there in fact is an
16:46:17 13 increased odds ratio; correct?

16:46:19 14 A. For -- for --

16:46:21 15 Q. The use of the device and the outcome of
16:46:23 16 infection.

16:46:24 17 A. The use of the device. It would give a
16:46:26 18 better estimate of that, yes.

16:46:27 19 Q. Okay. The recent Augustine study does that;
16:46:30 20 correct?

16:46:30 21 A. The -- this is the published -- the one that
16:46:34 22 was just published?

16:46:35 23 Q. Yeah.

16:46:36 24 A. Well, I mean the recent study has its own --
16:46:41 25 has a -- has the potential for bias that is also in

16:46:48 1 McGovern.

16:46:48 2 Q. Okay. But my question is different. The
16:46:51 3 recent Augustine article has a larger patient
16:46:54 4 population; --

16:46:55 5 A. It's a larger patient population.

6 Q. -- correct?

7 A. It is a larger patient population. I think
16:46:58 8 it is, yes.

16:46:58 9 Q. And the article notes that there was no
10 change in the thromboprophylaxis or the antibiotic
16:47:05 11 regimen; correct?

16:47:05 12 MR. GORDON: Object to the form of the
16:47:06 13 question, assumes facts -- mis -- it completely
16:47:08 14 misstates the evidence.

16:47:11 15 A. I -- the -- the --

16:47:13 16 The paper says very little about -- very --
16:47:19 17 very little detailed about -- about -- about the
16:47:21 18 population. I think it says that, yes.

16:47:23 19 Q. Okay. So we've established that it's a
16:47:25 20 larger population and that the study does say that
16:47:28 21 there was not a change in the thromboprophylaxis or
16:47:31 22 antibiotic; is that correct?

16:47:32 23 MR. GORDON: Counsel, it doesn't -- it
16:47:33 24 doesn't say that. Let him read it if you're going to,
16:47:36 25 you know, make it up, make up stuff.

16:47:39 1 THE WITNESS: Where specifically does it say
16:47:41 2 that?
16:47:42 3 MR. SACCHET: Okay.
16:47:56 4 THE WITNESS: Have you got it?
16:47:56 5 (Exhibit 28 was marked for
16:47:58 6 identification.)
16:47:58 7 BY MR. SACCHET:
16:47:59 8 Q. Is this a copy of the recent Augustine
16:48:02 9 publication in Orthopedic Reviews?
16:48:04 10 A. Yes, it is.
16:48:04 11 Q. Okay. We can see that on page one there is
16:48:09 12 a subject header entitled "Materials and Methods;"
16:48:11 13 correct?
16:48:11 14 A. Yes.
16:48:14 15 Q. In the bottom right-hand corner.
16:48:15 16 And it says, "This study is designed to
16:48:19 17 investigate periprosthetic joint infection (PJI) rates
16:48:22 18 while using FAW (Bair Hugger, 3M, St. Paul, Minnesota,
16:48:25 19 USA) compared with air-free CFW (HotDog, Augustine
16:48:31 20 Temperature Management, Eden Prairie, USA);" correct?
16:48:33 21 A. Yes.
16:48:34 22 Q. The next paragraph says, "Each hospital
16:48:37 23 report shares a study design similar to the McGovern
16:48:37 24 study;" correct?
16:48:38 25 A. Yes.

16:48:39 1 Q. "In each study, a baseline PJI rate was
16:48:42 2 determined for the FAW control group over a one-year
16:48:45 3 period of time. FAW was then discontinued, and the
16:48:48 4 hospital switched to air-free CFW warming;" correct?

16:48:52 5 A. Yes.

16:48:53 6 Q. Okay. The top of the next column says,
16:48:55 7 "Only hospitals reporting that no other significant
16:48:59 8 changes were made to their surgical and antibiotic
16:49:01 9 prophylaxis protocols during the study period
16:49:04 10 qualified to be part of this study." Do you see that?

16:49:07 11 A. Yes.

16:49:11 12 Q. It says that there were no changes to
16:49:13 13 antibiotic prophylaxis protocols; correct?

16:49:15 14 A. That's what it says, yes.

16:49:17 15 Q. Do you have any reason to doubt that?

16:49:21 16 A. I -- I don't know. I mean that's what --
16:49:24 17 that's what it says. I don't -- it -- it --

16:49:27 18 I mean we have very little detail here
16:49:29 19 about -- about any variables other than the -- other
16:49:36 20 than the device that was used --

16:49:37 21 Q. Okay. Do you have any --

16:49:39 22 A. -- on the patients or --

16:49:42 23 I mean there's no table here giving basic
16:49:50 24 demographics about the -- about the patient
16:49:53 25 population.

16:49:54 1 Q. Demographics are different than whether
16:49:56 2 there were changes to the surgical and antibiotic
16:49:58 3 prophylaxis protocols; correct?

16:50:00 4 A. They are diff -- they are, but I mean all --
16:50:04 5 all I'm -- all I'm indicating is that details --

16:50:06 6 Q. Okay.

16:50:06 7 A. -- related to what was done in this study
16:50:08 8 are pretty skimpy.

16:50:10 9 Q. Have you tried to investigate the details
16:50:12 10 that you would otherwise like to know?

16:50:13 11 A. Oh. I mean you can look at any other paper.
16:50:17 12 I mean there's lots of reports on the -- on the -- on
16:50:20 13 the characteristics of the patients, what's the age
16:50:23 14 distribution of the patients that they're looking
16:50:25 15 at, --

16:50:25 16 Q. Have you contact --

16:50:26 17 A. -- how many males, how many females there
16:50:29 18 were, --

16:50:29 19 Q. Okay.

16:50:29 20 A. -- what is the racial distribution of the --

21 Q. Okay.

16:50:30 22 A. -- of the -- of the paper. I mean there's
16:50:31 23 a -- the --

16:50:32 24 The list of things that are not here --

16:50:35 25 Q. Okay.

16:50:36 1 A. -- is pretty remarkable.

16:50:37 2 Q. What is here? There's a statement that says
16:50:40 3 "Only hospitals reporting that no other significant
16:50:42 4 changes were made to their surgical and antibiotic
16:50:45 5 prophylaxis protocols during the study period
16:50:48 6 qualified to be part of this study."

16:50:49 7 A. Okay.

16:50:50 8 Q. Do you have any basis, scientific or
16:50:52 9 otherwise, to doubt the veracity of that statement?

16:50:55 10 A. No.

16:50:55 11 Q. If we look at Table 1, there are three
16:50:59 12 centers denominated in the table; correct?

16:51:02 13 A. That's correct.

16:51:03 14 Q. And the first center has broken down between
16:51:09 15 conductive fabric and forced air; correct?

16:51:12 16 A. Yes.

16:51:12 17 Q. And the odds ratio, based on the increase in
16:51:14 18 infection from the use of forced air instead of
16:51:17 19 conductive fabric, is 4.59 as reported in this study;
16:51:21 20 correct?

16:51:21 21 A. That's what they report, yeah.

16:51:22 22 Q. Okay. That's the question.

16:51:24 23 The second center also evaluates the change
16:51:27 24 from conductive fabric to forced air and it finds an
16:51:30 25 odds ratio of 11.47 as reported in Table 1; correct?

16:51:34 1 A. That's what they report.

16:51:36 2 Q. Both of those odds ratios are higher than
16:51:38 3 what was reported in the McGovern study; correct?

16:51:41 4 A. That's true.

16:51:42 5 Q. The second odds ratio of 11.47 is almost
16:51:49 6 three times the size of what was reported in the
16:51:52 7 McGovern study; correct?

16:51:55 8 A. That's the -- the --

16:51:57 9 You're -- you're referring to just the point
16:51:59 10 estimate.

16:51:59 11 Q. Just the odds ratio.

16:52:00 12 A. Just the point estimate.

16:52:02 13 Q. Yeah, that's the question.

16:52:03 14 A. It is large. It is large, yes.

16:52:04 15 Q. Okay. And the center three, in all
16:52:09 16 fairness, reported a 1.33 odds ratio; correct?

16:52:11 17 A. That's right.

16:52:12 18 Q. The multi-center pooled results based on
16:52:14 19 those three institutions totaling a population of over
16:52:20 20 2,000 persons --

16:52:21 21 Correct?

16:52:22 22 A. Yes.

16:52:23 23 Q. -- found a collective odds ratio of 4.28;
16:52:27 24 correct?

16:52:27 25 A. That's right.

16:52:27 1 Q. That is higher than what's reported in the
16:52:29 2 McGovern study; correct?

16:52:30 3 A. That point estimate is higher.

16:52:31 4 Q. It's doubled in the size of the odds ratio
16:52:34 5 of 2.16 that you reported in your study.

16:52:37 6 A. It's twice -- twice that, yes.

16:52:39 7 Q. It's four times the size of the odds ratio
16:52:42 8 that you reported when controlling for both the
16:52:44 9 thromboprophylaxis and the antibiotic; correct?

16:52:46 10 A. That's correct.

16:52:47 11 Q. The population is four times the size.

16:52:51 12 A. That's --

16:52:53 13 Is it four times?

16:52:55 14 Q. Your population was approximately 600
16:52:57 15 persons.

16:52:57 16 A. Oh, oh, I see that's how you use that.

16:53:00 17 Yeah, that's true. Yes.

16:53:01 18 Q. Okay. Based on this size of the
16:53:03 19 population -- well strike that.

16:53:08 20 The p-value for the multi-center pooled
16:53:11 21 result is .002; correct?

16:53:13 22 A. That's right.

16:53:14 23 Q. That is a statistically significant p-value;
16:53:18 24 correct?

16:53:18 25 A. That is. The -- the -- the confidence

16:53:23 1 interval is still 10.

16:53:27 2 Q. It's half the size of the confidence
16:53:29 3 interval you reported in the Jensen reanalysis;
16:53:33 4 correct?

16:53:33 5 A. The --

16:53:34 6 For that particular association, yes. But
16:53:37 7 it's not that different from the confidence interval
16:53:40 8 that was reported in McGovern.

16:53:43 9 Q. Okay. If we could --

16:53:53 10 A. May I --

16:53:54 11 There are other aspects of this -- of
16:53:57 12 this -- of this --

16:53:57 13 Q. I haven't asked about them, so perhaps --

16:54:00 14 A. I know you haven't asked about them, but
16:54:01 15 you --

16:54:01 16 Q. -- perhaps you can explain them when Mr.
16:54:04 17 Gordon --

16:54:04 18 A. Okay.

16:54:06 19 Q. -- asks you some questions.

16:54:07 20 With respect to the conclusions that you
16:54:08 21 offer in the epi section of your report --

16:54:14 22 MR. GORDON: What section?

16:54:15 23 Q. -- the epidemiology section of your report
16:54:17 24 regarding drawing causal inferences, there is that
16:54:20 25 part of your report; right?

16:54:20 1 A. Yes.

16:54:21 2 Q. Okay.

16:54:36 3 MR. GORDON: Are you talking about

16:54:37 4 "Causation findings," that section?

16:54:39 5 THE WITNESS: Yeah, I think that's what he's

16:54:41 6 citing.

16:54:41 7 MR. SACCHET: Yeah. That was inartful.

16:54:43 8 Q. The first factor that you analyzed was the

16:54:46 9 temporality --

16:54:47 10 A. Yeah.

16:54:48 11 Q. -- of -- of this -- of this data.

16:54:54 12 You agree that temporality is met with

16:54:57 13 respect to the Bair Hugger and the risk of increased

16:55:01 14 infection, however; correct?

16:55:02 15 A. Yes, I do.

16:55:03 16 Q. Okay. You also assume that it's possible

16:55:05 17 that temporality may be met with respect to the

16:55:07 18 thromboprophylaxis; correct?

16:55:09 19 A. Yes.

16:55:10 20 Q. We discussed earlier that the McGovern study

16:55:13 21 states that the thromboprophylaxis is applied

16:55:16 22 postoperatively; correct?

16:55:17 23 A. Yes.

16:55:18 24 Q. You --

16:55:20 25 Do you know the rate in which an infection

16:55:22 1 forms on a prosthetic upon a bacteria landing on the
16:55:29 2 prosthetic?

16:55:30 3 Let me rephrase. It was not a good
16:55:32 4 question.

16:55:32 5 Do you know how quickly an infection may
16:55:36 6 manifest after a bacteria lands on a prosthetic
16:55:39 7 implant?

16:55:41 8 A. No, I don't. I mean I -- the --

16:55:50 9 Using the -- this part of the -- the
16:55:56 10 protocol, it is the same for -- for -- for McGovern's
16:56:04 11 study as it was for, you know, the Jensen study,
16:56:08 12 and -- and so they were -- they were using the same
16:56:12 13 method, so whatever the temporality is related to that
16:56:15 14 variable I assume is about the same.

16:56:17 15 Q. So my question, though, is: You don't know
16:56:20 16 whether or not a deep joint infection could occur
16:56:23 17 within an hour of a bacteria landing on the implant.

16:56:28 18 A. Could it have -- I'm not --

16:56:32 19 I don't know how long it takes. It often --
16:56:35 20 it -- it may take longer, and may take longer for the
16:56:38 21 diagnosis to come -- come in.

16:56:40 22 Q. It could be shorter than an hour.

16:56:41 23 MR. GORDON: Objection, lack of foundation.

16:56:43 24 A. I don't -- I don't know how long it takes.

16:56:46 25 Q. You don't know.

16:56:46 1 A. It's not -- it's not reported. I think it's
16:56:48 2 reported how long after the surgery --
16:56:50 3 Q. Up to 60 days; correct?
16:56:53 4 A. Up to 60 days. But some of that I assume is
16:56:56 5 lab time and all that stuff.
16:56:58 6 Q. Yeah.
16:56:59 7 A. And so who knows?
16:57:00 8 Q. Okay.
16:57:01 9 A. It's not addressing the question that you're
16:57:03 10 asking I don't think.
16:57:03 11 Q. Well -- yeah. So my question really is: To
16:57:06 12 the extent that a deep joint infection may occur
16:57:10 13 within a matter of hours after surgery, temporality is
16:57:14 14 not met in the event that the thromboprophylaxis is
16:57:18 15 applied a day after the surgery.
16:57:20 16 A. If it occurs within hours. Well I mean --
16:57:26 17 Q. The bacteria causes an infection within a
16:57:28 18 matter of hours --
16:57:30 19 A. Yeah, but it -- what --
16:57:32 20 You're not observing it until 60 days later.
16:57:39 21 Q. That's possible. But of course --
16:57:41 22 A. So if you're observing it at that point --
16:57:43 23 I mean the infection could have started
16:57:45 24 within hours and then you apply the -- imply
16:57:50 25 the -- apply the -- the anti -- antibiotic and it

16:57:55 1 kills whatever happened to be there.

16:57:56 2 Q. You're talking about the thromboprophylaxis,
16:57:59 3 which is a blood thinner; correct?

16:58:00 4 A. Okay. The blood thinner, whatever effect
16:58:02 5 that is having.

16:58:03 6 Q. Yeah.

16:58:03 7 A. I don't know --

16:58:04 8 Q. You don't know whether there is an effect.

16:58:05 9 A. Don't -- I --

16:58:06 10 I don't know. There is an association --

16:58:08 11 Q. Okay.

16:58:08 12 A. -- in -- in this particular study, --

16:58:10 13 Q. Okay.

16:58:11 14 A. -- so that -- which -- which would suggest
16:58:15 15 if it's not a causal effect, it's at least -- it's --
16:58:22 16 it's confounded by the same types of factors that
16:58:25 17 could be confounding the association that -- that --
16:58:30 18 with the device that's being reported by McGovern.

16:58:32 19 Q. But in the event that an infection does in
16:58:34 20 fact occur within hours of a surgery, application of a
16:58:40 21 thromboprophylaxis a day later does not satisfy
16:58:44 22 temporality.

16:58:45 23 MR. GORDON: Objection, lack of foundation,
16:58:48 24 incomplete hypothetical, assumes facts not in
16:58:51 25 evidence.

16:58:54 1 A. I didn't analyze the temporal -- the -- how
16:58:59 2 long it took for the -- for the -- how -- when -- when
16:59:03 3 the infection -- infection occurred.

16:59:06 4 Q. Uh-huh.

16:59:06 5 A. Those data I don't think were reported on --
16:59:11 6 on the data that I was looking at.

16:59:12 7 Q. So you don't know whether temporal --

16:59:14 8 A. So I don't know whether the in -- there was
16:59:17 9 an infection at that point in time. I -- the data --

16:59:22 10 When I compared the dates of the diagnosis
16:59:24 11 to when the surgery was done, I don't recall there
16:59:30 12 being -- I mean I went over the inci -- incidences, I
16:59:35 13 don't recall instances where they were diagnosed on
16:59:37 14 the same day.

16:59:38 15 Q. Okay. But you're not sure whether
16:59:41 16 temporality is satisfied in all cases with respect to
16:59:44 17 the thromboprophylaxis because you don't know how
16:59:46 18 quickly an infection manifests; is that true?

16:59:50 19 A. I -- I didn't specifically look at that. I
16:59:53 20 suspected that it was, but it -- it -- it -- it --
16:59:58 21 it -- it's possible that it wasn't.

16:59:59 22 Q. You don't know.

16:59:59 23 A. I -- I don't know. I don't -- I don't know.

17:00:01 24 Q. Okay.

17:00:02 25 A. But there again, I mean the temporality is

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17:00:08 1 important for finding the association for what
17:00:11 2 occurred during the time period that -- that the
17:00:16 3 particular form of prophylaxis was applied, because
17:00:20 4 that could be -- it -- it could be in fact due to
17:00:25 5 something else because of the way this study was done.
17:00:30 6 It was only done by looking at certain dates. So what
17:00:33 7 happened? And of course a lot of things could be
17:00:35 8 happening during these dates, because as -- as the --
17:00:45 9 this -- this study is related to --

17:00:47 10 All the changes that were taking place with
17:00:50 11 regard to SSI, which quite possibly were also
17:00:56 12 affecting the -- the -- the deep joint infections,
17:01:01 13 were taking place during this time period, and so
17:01:07 14 that -- it could be something in that that is being
17:01:12 15 indirectly controlled when I'm controlling for the
17:01:14 16 thromboprophylaxis.

17:01:15 17 Q. The bottom line is that there's no doubt
17:01:18 18 temporality is satisfied with respect to the Bair
17:01:20 19 Hugger and incidence of infection; however, there is
17:01:22 20 potential doubt with respect to any of the other
17:01:24 21 factors that you've noted in your report.

17:01:26 22 MR. GORDON: Object to the form of the
17:01:27 23 question, lack of foundation, assumes facts not in
17:01:29 24 evidence.

17:01:34 25 A. There is -- there's the potential --

17:01:37 1 Q. Let me ask the question again. There's no
17:01:39 2 question that temporality is satisfied with respect to
17:01:43 3 the Bair Hugger. You've said as much in your report.

17:01:44 4 A. Yes.

17:01:45 5 Q. There is a question as to whether
17:01:47 6 temporality is satisfied with respect to the
17:01:50 7 thromboprophylaxis and any other of the -- of the
17:01:52 8 measures that were part of the SSI bundle.

17:01:55 9 MR. GORDON: Same objections.

17:01:57 10 Q. You don't know whether temporality is
17:02:00 11 satisfied as to those variables; do you?

17:02:05 12 A. With regard to --

17:02:07 13 Q. The thromboprophylaxis. Do you know?

17:02:09 14 A. -- thromboprophylaxis --

17:02:11 15 Q. Do you know?

17:02:12 16 A. I don't know exactly when it -- when it
17:02:14 17 was -- we --

17:02:14 18 We don't have data on the timing --

17:02:16 19 Q. Okay.

17:02:16 20 A. -- of it, but --

17:02:19 21 Q. So you don't know.

17:02:19 22 A. So --

17:02:21 23 Q. It's really "yes" or "no."

17:02:26 24 A. I --

17:02:28 25 Well I don't have sufficient detail to

17:02:30 1 really -- to really be able to -- to -- to nail it

17:02:33 2 down --

17:02:34 3 Q. Okay.

17:02:34 4 A. -- as to when it is. I --

17:02:36 5 Q. Thank you.

17:02:37 6 A. I suspect it probably is, but it's unclear.

17:02:41 7 And I think I say -- well it -- it's --

17:02:47 8 I think it's potentially controlled for,

17:02:49 9 yes.

17:02:49 10 Q. Okay.

17:02:49 11 A. It's not --

17:02:50 12 Q. It's unclear.

17:02:52 13 A. Yes.

17:02:54 14 Q. The second factor with respect to causal

17:02:56 15 inference is the strength of association; correct?

17:02:58 16 A. Yes.

17:03:01 17 Q. And as to that factor, unlike temporality,

17:03:05 18 it is not a prerequisite to drawing causal inference;

17:03:17 19 correct?

17:03:17 20 A. Well it helps to -- to establish that the

17:03:22 21 association is temp -- is -- is in fact causal because

17:03:27 22 otherwise it could easily be confounded with something

17:03:29 23 else.

17:03:29 24 Q. It helps, but it is not required as it is in

17:03:32 25 temporality; correct?

17:03:34 1 A. Well it's one of the factors that's looked
17:03:36 2 for, and in fact one of the factors that was addressed
17:03:39 3 that -- that Samet uses.

17:03:42 4 Q. The question is different and that is:
17:03:44 5 Temporality is a required factor to draw causal
17:03:47 6 inference; correct?

17:03:48 7 A. Yes.

17:03:49 8 Q. The strength of association --

17:03:51 9 A. Is another factor that --

17:03:53 10 Q. -- is another factor, but is not a
17:03:55 11 prerequisite for drawing causal inference.

17:04:00 12 A. Okay.

17:04:00 13 Q. Okay. The strength of association goes to
17:04:05 14 the magnitude of causation as opposed to the presence
17:04:08 15 of causation; correct?

17:04:10 16 MR. GORDON: Object to the form of the
17:04:11 17 question.

17:04:14 18 Q. You stated earlier --

17:04:15 19 A. It's not looking at the mag -- but the --

17:04:18 20 I don't know what you mean by the magnitude
17:04:20 21 of the causation.

17:04:20 22 Q. The odds --

17:04:21 23 A. It's either causing or it's not causing.

17:04:24 24 Q. The odds ratio --

17:04:25 25 A. The association has a magnitude, so I'm not

17:04:27 1 sure what you're --

17:04:29 2 Q. Okay.

17:04:30 3 A. -- what you're saying.

17:04:30 4 Q. Is the association measured by the odds
17:04:32 5 ratio?

17:04:32 6 A. The magnitude of association, yes.

17:04:36 7 Q. Yes. So with respect to a number such as
17:04:38 8 3.8, that signifies the magnitude of the association
17:04:42 9 as reported in McGovern.

17:04:44 10 A. That -- that -- that is a point estimate of
17:04:46 11 magnitude --

12 Q. Okay.

17:04:46 13 A. -- of association, yes.

17:04:47 14 Q. Okay. And that's different than a simple
17:04:49 15 determination of causation.

17:04:51 16 A. Yes. It's, of course, not just the point
17:05:00 17 estimate, --

17:05:00 18 Q. Yes.

17:05:00 19 A. -- it's the precision of the estimate, so
17:05:02 20 you have to take into account the confidence interval
17:05:05 21 as well.

17:05:05 22 Q. An odds ratio of less than two can show
17:05:07 23 causation; correct?

17:05:11 24 A. It -- it might, yes.

17:05:12 25 Q. Yes.

17:05:14 1 And you report that the odds ratio with
17:05:25 2 respect to Albrecht 10 using Fisher's exact is 2.76;
17:05:31 3 correct?

17:05:31 4 A. Yes.

17:05:32 5 Q. You also report that the odds ratio when
17:05:35 6 applying one additional infection in each arm of the
17:05:41 7 study, according to Mr. Reed's testimony, results in
17:05:43 8 an odds ratio of 2.89; correct?

17:05:48 9 A. I think so.

17:05:50 10 Q. Footnote one of your report.

17:05:57 11 A. I think that's right. I presume --

17:05:58 12 Well 2.886 actually I think it is. Yes.

17:06:01 13 Q. That's --

17:06:02 14 Oh, my apologies. I said 2.89.

17:06:04 15 With respect to when you control for the
17:06:06 16 thromboprophylaxis using Albrecht Exhibit 10, the odds
17:06:10 17 ratio is 2.16; correct?

17:06:12 18 A. Yes, I think it's right.

17:06:18 19 Q. You did not report an odds ratio when only
17:06:21 20 controlling for the antibiotic; correct?

17:06:23 21 A. That's correct.

17:06:25 22 Q. Aside from when you controlled both
17:06:27 23 variables, all of the odds ratios that we just
17:06:30 24 discussed are above 2.0; correct?

17:06:33 25 A. All of those, yes.

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17:06:34 1 Q. Okay. And as we've established, if an odds
17:06:38 2 ratio is above 2.0, that signifies a doubling of the
17:06:42 3 risk; correct?

17:06:43 4 A. For the point estimate.

17:06:44 5 Q. Okay.

17:06:45 6 A. That's --

17:06:47 7 The precision of that estimate is obviously
17:06:51 8 also relevant.

17:06:52 9 Q. Yeah. And the Augustine 2007 paper reports
17:07:00 10 an odds ratio for the multi-center data above four;
17:07:04 11 right? I believe that's what it was.

17:07:05 12 A. That's what's reported, yes.

17:07:07 13 Q. Okay.

17:07:15 14 MR. SACCHET: Can I have a time check, Mr.
17:07:16 15 Stirewalt?

17:07:19 16 THE VIDEOGRAPHER: Six hours and 20 minutes
17:07:24 17 we've been going, forty minutes remaining.

17:07:36 18 Q. Are you aware of the difference in the legal
17:07:38 19 standard versus scientific standard for drawing causal
17:07:43 20 inference?

17:07:44 21 MR. GORDON: Objection, object to the form,
17:07:47 22 also lack of foundation.

17:07:53 23 A. I'm not -- I don't -- not sure what you're
17:07:55 24 asking.

17:07:56 25 Q. Do you know whether as a matter of law it's

17:08:00 1 okay to rely on one observational study --

17:08:03 2 MR. GORDON: Same --

17:08:05 3 Q. -- to prove causation?

17:08:07 4 MR. GORDON: Same objection.

17:08:07 5 A. I am not a lawyer, I've not studied law, so

17:08:13 6 I'm not -- I don't know what the -- what the

17:08:16 7 definitions are that are used.

17:08:18 8 Q. You didn't opine on that in your report;

17:08:22 9 correct?

17:08:22 10 A. No. No.

17:08:22 11 Q. Okay. With respect to the variable of

17:08:25 12 consistency, which is the third factor that both you

17:08:30 13 and Dr. Samet considered with respect to causal

17:08:33 14 inference, even inconsistent results do not rule out

17:08:40 15 causal nexus; correct?

17:08:42 16 MR. GORDON: Object to the form of the

17:08:43 17 question.

17:08:50 18 A. What do you --

17:08:52 19 If they're inconsistent, then it -- it's

17:08:58 20 going -- going to make it more difficult to determine

17:09:03 21 that the association is -- is causal.

17:09:05 22 Q. But you can still draw a causal inference

17:09:08 23 even with inconsistent results.

17:09:09 24 MR. GORDON: Same objection.

17:09:12 25 A. It really depends on what -- what you're

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17:09:15 1 looking at. I mean in the abstract I don't -- I have
17:09:17 2 a hard time of knowing exactly what you're talking
17:09:20 3 about.

17:09:20 4 Q. Do you agree with the statement provided in
17:09:22 5 The Reference Manual on Epidemiology that inconsistent
17:09:26 6 results do not necessarily rule out a causal nexus?

17:09:29 7 A. Yes.

17:09:30 8 Q. You disagree with that?

17:09:31 9 A. No, I would agree with that.

17:09:33 10 Q. You agree with that.

17:09:34 11 A. Yes.

17:09:34 12 Q. Okay. Are you aware of any inconsistent
17:09:39 13 results with respect to the Bair Hugger causing deep
17:09:46 14 joint infections?

17:09:53 15 A. I -- I'm not --

17:09:56 16 I don't agree with the idea that it -- it --
17:09:58 17 that the causality has been established. If what
17:10:02 18 you're asking for is consistency of the
17:10:07 19 association, --

17:10:07 20 Q. I can rephrase.

17:10:09 21 A. -- that -- that's a little different.
17:10:12 22 That's -- certainly the --

17:10:16 23 I mean basically what we have is the
17:10:19 24 Augustine paper and the McGovern paper. Those
17:10:22 25 published associations are -- are consistent.

17:10:27 1 Q. So there are two studies and they're both
17:10:29 2 consistent; correct?

17:10:30 3 A. Those two studies agree with each other,
17:10:32 4 apparently.

17:10:33 5 Q. Are you aware of any other observational
17:10:36 6 studies that have been conducted that are inconsistent
17:10:38 7 with those two studies?

17:10:39 8 A. Those are the only studies that I'm aware of
17:10:41 9 that have been -- that -- that have compared Bair
17:10:44 10 Hugger and Hot Dog.

17:10:46 11 Q. Are you aware of any mechanistic studies
17:10:48 12 that have been published that are inconsistent with
17:10:50 13 the fact that the Bair Hugger increases the risk of
17:10:53 14 deep joint infection?

17:10:54 15 MR. GORDON: Object to the form of the
17:10:55 16 question.

17:10:58 17 A. These are the only two studies that I -- I
17:11:02 18 think I said that I know of that have looked at that
17:11:05 19 association --

17:11:06 20 Q. Okay.

17:11:06 21 A. -- between use of the -- of -- the type of
17:11:11 22 warming device that was used and risk of infection --
17:11:14 23 of deep infection.

17:11:15 24 Q. Are you aware of any studies regarding the
17:11:17 25 Bair Hugger that show the device does not increase the

17:11:23 1 amount of particles over the surgical site?

17:11:25 2 MR. GORDON: Object to the form of the
17:11:26 3 question, lack of foundation.

17:11:29 4 A. That does not --

17:11:31 5 Q. Increase particles over the surgical site.

17:11:36 6 A. Well if you're talking about --

17:11:38 7 You're reducing it then for particles. I
17:11:42 8 mean we -- we've talked about --

17:11:43 9 Q. Yeah. I'm just asking just this question.

17:11:45 10 A. -- discussed all of that on the record --

17:11:47 11 Q. Just this question.

17:11:47 12 A. -- and I'm --

17:11:50 13 I mean there have been several studies that
17:11:52 14 have looked at particle distribution associated with
17:11:56 15 the -- with the -- with the use of Bair -- Bair
17:11:57 16 Hugger.

17:11:57 17 Q. The question is: Are you aware of any
17:12:00 18 studies that do not show an increase in particles over
17:12:03 19 the surgical site from the Bair Hugger? That's the
17:12:05 20 question. "Yes" or "no."

17:12:08 21 MR. GORDON: Same objection.

17:12:11 22 A. I have not -- haven't really investigated
17:12:14 23 that -- that field of how -- of what all the studies
17:12:17 24 are --

17:12:18 25 Q. On what basis --

17:12:19 1 A. -- that have looked at that.

17:12:20 2 Q. On what basis do you conclude, then, that
17:12:23 3 there is any consistency, if any, with respect to the
17:12:29 4 risk of infection posed by the Bair Hugger?

17:12:32 5 MR. GORDON: Object to the form of the
17:12:33 6 question.

17:12:38 7 A. I -- I mean I think what I was -- what I
17:12:41 8 said in my report is that there's --

17:12:44 9 Well, at the time this was written --

17:12:45 10 Q. One study, yeah.

17:12:47 11 A. -- there was one study.

17:12:49 12 Q. That no longer applies; correct?

17:12:49 13 A. There's -- there's now two.

17:12:50 14 Q. And you've just said that those two studies
17:12:52 15 are consistent.

17:12:53 16 A. Those two studies made the same mistakes and
17:12:57 17 they found similar magnitudes of association, so
17:13:03 18 that's --

17:13:04 19 So now there is a consistency of two.

17:13:06 20 Q. Okay. So you're --

17:13:09 21 A. Samet was talking about -- was comparing the
17:13:11 22 situation of Bair Hugger to cigarettes.

17:13:13 23 Q. Could you show me where he does that?

17:13:17 24 A. Oh --

17:13:18 25 MR. GORDON: Did you mark Samet already?

17:13:20 1 MR. SACCHET: Yeah, I did. Exhibit 3.

17:13:25 2 A. I mean he uses cigarettes -- he -- he talks
17:13:28 3 about cigarettes, and that's basically the -- the
17:13:33 4 analogy that he is using where he's looking at that
17:13:36 5 association.

17:13:37 6 Q. Where does he do that?

17:13:56 7 A. Okay. Exhibit 3.

17:14:13 8 Q. I can speed this up for you, Professor
17:14:16 9 Holford, and -- and show you the two places that Dr.
17:14:20 10 Samet references tobacco, outside of his history, in
17:14:24 11 uncovering the link between tobacco use and cancer, if
17:14:28 12 that would be helpful.

17:14:29 13 A. Okay.

17:14:31 14 Q. On page 10, Dr. Samet says in the second --
17:14:45 15 or the first full paragraph, about halfway through,
17:14:51 16 "For example, observational designs were used in
17:14:54 17 linking cigarette smoking to lung cancer, as some
17:14:58 18 people were either current or former smokers and
17:15:00 19 others had never smoked. Two basic designs were used;
17:15:05 20 the case-control study..." And he goes on to
17:15:06 21 explain --

17:15:07 22 A. Uh-huh.

17:15:07 23 Q. -- those types of studies; correct?

17:15:09 24 A. Yes.

17:15:09 25 Q. That's one example.

17:15:10 1 A. Yeah.

17:15:11 2 Q. The second example is on page 11, in the
17:15:15 3 third paragraph, in the last sentence, which says,
17:15:19 4 "These arguments are the typical general claims made
17:15:21 5 by those seeking alternative explanations for an
17:15:24 6 association, and reach back to the strategies employed
17:15:27 7 for decades by the tobacco industry," citing Proctor,
17:15:33 8 2012 and Samet and Burke, 2001; correct?

17:15:33 9 A. Yes.

17:15:34 10 Q. Are you aware of any other references to
17:15:37 11 tobacco that Dr. Samet makes outside of the first
17:15:40 12 three or four pages of the report which describes his
17:15:43 13 background?

17:15:46 14 A. Well I mean he --

17:15:48 15 In this part of his report he is, I think,
17:15:52 16 using tobacco as -- I mean it's under the section
17:15:58 17 entitled "Evidence Synthesis and Findings on
17:16:02 18 Causation."

17:16:02 19 Q. Okay.

17:16:02 20 A. So this is forming the basis that he's using
17:16:05 21 for his justification of causation.

17:16:08 22 Q. Where does he link the causation in tobacco
17:16:13 23 to causation with the Bair Hugger? Where is that
17:16:17 24 express link in this report?

17:16:19 25 A. Well no, the point is not that he's -- that

17:16:22 1 those two are --

17:16:23 2 He's using tobacco, the experience with
17:16:28 3 tobacco in showing the causal association with tobacco
17:16:34 4 and -- as I understand it, to try to argue that
17:16:37 5 there's a causal association between a warming device
17:16:41 6 and the risk of in -- of deep infection.

17:16:43 7 Q. So those two sentences in the 17-page report
17:16:47 8 in your view show that Dr. Samet is linking tobacco to
17:16:51 9 the Bair Hugger.

17:16:52 10 A. Well it's not just those --

17:16:53 11 MR. GORDON: No, no, no. Take -- take the
17:16:54 12 time and go through it page by page and -- and --
17:16:56 13 and --

17:16:56 14 MR. SACCHET: We don't have time for that.

17:16:57 15 MR. GORDON: Well then -- no. Then you're
17:16:59 16 not going to just tell him what you've decided are the
17:17:03 17 only two sentences and -- and -- and then get him to
17:17:06 18 say -- to agree that those are the only two sentences.

17:17:08 19 Q. Do you have a recollection to the contrary?
17:17:09 20 I've gone through this report and I have made a great
17:17:11 21 effort to isolate those two sentences that are the
17:17:14 22 only two in my view that exist outside of the
17:17:16 23 background section of this report in which Dr. Samet
17:17:20 24 describes that he was a senior scientific editor of
17:17:23 25 both the 2004 and 2014 report to the Surgeon General

17:17:24 1 regarding the incidence of cancer with respect to
17:17:25 2 tobacco use, along with being an associate editor of
17:17:28 3 the 1986 report to the Surgeon General. Are you aware
17:17:31 4 of any other statement?

17:17:31 5 MR. GORDON: Well -- well great, counsel,
17:17:34 6 then you have all you need to know about your views.

17:17:36 7 MR. SACCHET: Okay.

17:17:36 8 MR. GORDON: If you want to know Dr.
17:17:38 9 Holford's views, he's not going to rely on your
17:17:40 10 representation of your views, he's going to go through
17:17:42 11 the document and --

17:17:43 12 Q. Sitting here today, do you have any
17:17:45 13 recollection of any other statements that Dr. Samet
17:17:48 14 has made linking the use of tobacco and the incidence
17:17:51 15 of cancer to the use of the Bair Hugger and deep joint
17:17:54 16 infection, sitting here right now?

17:17:55 17 MR. GORDON: If you want him to answer that
17:17:56 18 question, he will go through the report. If you don't
19 want --

17:17:59 20 MR. SACCHET: You just want me to do that,
17:18:00 21 Corey, to use the rest of the time, which I'm not
17:18:03 22 going to do.

17:18:04 23 MR. GORDON: No. If you don't want a -- if
17:18:05 24 you don't want an answer to the question, withdraw it
17:18:08 25 and move on.

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17:18:08 1 Q. I'm asking right now: Sitting here today,
17:18:10 2 are you aware of any other statements?

17:18:11 3 MR. GORDON: I'm not going to let him answer
17:18:13 4 that question --

17:18:14 5 MR. SACCHET: You're going to instruct him
17:18:15 6 not to answer?

17:18:16 7 MR. GORDON: Yeah, I'm going to instruct him
17:18:18 8 not to answer.

17:18:19 9 MR. SACCHET: Okay. Noted for the record.
17:18:21 10 I'll move on.

11 MR. GORDON: If you want him to answer the
12 question, he will go through the report and -- and
17:18:23 13 answer it.

17:18:23 14 Q. Do you agree with Dr. Borak that the
17:18:24 15 particles are relevant to determining the coherency of
17:18:29 16 the scientific evidence to draw a causal inference?

17:18:31 17 MR. GORDON: Object to the form of the
17:18:33 18 question, lack of foundation, mischaracterizes the
17:18:35 19 evidence, assumes facts not in evidence.

17:18:38 20 THE REPORTER: We have 25 minutes left.

17:18:45 21 A. What was the question again? I -- I don't
17:18:47 22 understand --

17:18:48 23 Q. Do you agree with Dr. Borak that studies
17:18:51 24 involving particles are relevant to the factor of
17:18:56 25 coherency under the Bradford-Hill criteria?

17:19:00 1 MR. GORDON: Same objection.

17:19:00 2 A. I haven't seen the -- the Borak report, as

17:19:02 3 I --

17:19:02 4 Q. I'm not asking you whether you've seen it,

17:19:04 5 I'm asking whether you agree with Dr. Borak.

17:19:06 6 MR. GORDON: Well you're assuming that

17:19:08 7 you've --

8 A. Well then how can I --

17:19:08 9 MR. GORDON: -- accurately characterized

17:19:09 10 what he said. He -- he -- he lacks foundation,

17:19:11 11 counsel, he doesn't know what Dr. Borak said. If you

17:19:14 12 want to ask him if he agrees generally with his --

17:19:16 13 with whatever statement, you can ask him, but if

17:19:18 14 you're going to pin it on Dr. Borak, he doesn't have a

17:19:22 15 foundation to respond to that because he hasn't read

17:19:27 16 it.

17:19:27 17 Q. Do you disagree with this statement, "The

17:19:29 18 particle count studies might contribute to coherence?"

17:19:34 19 A. I -- I would need to get more of the

17:19:36 20 background of what that statement is -- is --

17:19:42 21 I mean you're taking one sentence out of --

17:19:44 22 of a whole report.

17:19:48 23 Q. Did you talk to Borak about your report?

17:19:51 24 A. No.

17:19:51 25 Q. Did you talk to Dr. Borak about his report?

17:19:54 1 A. No.

17:19:55 2 Q. You didn't meet with Dr. Borak on May 19th
17:19:58 3 in Washington, DC?

17:19:59 4 A. I did, but the --

17:20:02 5 Neither one of us, I think, had written a
17:20:04 6 report to that point.

17:20:06 7 Q. Did you talk about the substance of the
17:20:06 8 report prior to writing the report?

17:20:09 9 A. Of our report?

17:20:10 10 Q. Yeah.

17:20:10 11 A. We didn't discuss our own reports. Our
17:20:14 12 reports are our reports.

17:20:15 13 Q. What did you talk about at the May 19th
17:20:17 14 meeting?

17:20:20 15 A. Generally talked about how --

17:20:24 16 I mean we're in different fields, --

17:20:29 17 Q. I understand.

17:20:29 18 A. -- I mean, and so --

17:20:31 19 Q. Is your field specific to statistics and Dr.
17:20:35 20 Borak's is specific to epidemiology?

17:20:37 21 A. That's more of the division it would be --
17:20:38 22 it would be, I would say.

17:20:39 23 Q. Was the decision that you would opine on
17:20:41 24 statistics and Dr. Borak would respond on epi?

17:20:43 25 A. Well there is some -- some overlap, but I

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17:20:45 1 mean we were covering different parts of the -- parts
17:20:48 2 of the question, and so he's looking at -- he --

17:20:52 3 He is considering different issues than what
17:20:54 4 I considered.

17:20:55 5 Q. Well what did you talk about on May 19th?

17:21:01 6 A. Oh. You want me to generate minutes of the
17:21:04 7 meeting? Which I didn't at the -- at the time.

17:21:08 8 We were talking generally about -- about
17:21:13 9 basically how we -- what the issues were that we
17:21:16 10 would -- we would consider in our separate reports.

17:21:21 11 Q. And were there any issues with respect to
17:21:24 12 those views that either one of you were concerned
17:21:27 13 about?

17:21:28 14 MR. GORDON: Object to the form of the
17:21:29 15 question.

17:21:32 16 A. What -- what are you asking? I don't
17:21:34 17 understand the question.

17:21:34 18 Q. Were there any topics of conversation that
17:21:37 19 you were not comfortable with answering without
17:21:39 20 talking to Dr. Borak?

17:21:42 21 A. Not -- not in --

17:21:44 22 Not that I was looking at in my report, no.

17:21:46 23 Q. Okay. Were there any topics of conversation
17:21:51 24 that questioned whether the Bair Hugger does in fact
17:21:56 25 increase the rate of infection in deep joint

17:21:58 1 infections?

17:21:59 2 MR. GORDON: Object to the form of the
17:22:02 3 question.

17:22:04 4 A. What was the question again?

17:22:07 5 Q. Was there any conversation as to whether the
17:22:08 6 Bair Hugger does in fact increase the rate of deep
17:22:11 7 joint infection?

17:22:13 8 A. I mean there was general discussion about
17:22:17 9 what the -- what the association was and what --
17:22:21 10 what -- what the state of the evidence was on -- on
17:22:23 11 that association.

17:22:24 12 Q. Okay. Is it true that you decided that Dr.
17:22:27 13 Borak would be primarily responsible for the causal
17:22:31 14 inferences based on epidemiology and you would be
17:22:33 15 primarily responsible with respect to the statistical
17:22:36 16 application and reanalysis of the McGovern data?

17:22:39 17 MR. GORDON: Object to the form of the
17:22:40 18 question, also lack of foundation.

17:22:51 19 A. I'm not sure what you're asking. I --

17:22:54 20 Q. Did Dr. Borak ask you to help with drafting
17:22:58 21 a report or did 3M ask you?

17:23:00 22 A. 3M.

17:23:02 23 Q. They approached you independently of Dr.
17:23:05 24 Borak?

17:23:07 25 A. I think they may have gotten my name from

17:23:11 1 Dr. Borak, but --

17:23:12 2 Q. Okay.

17:23:13 3 A. -- we did not discuss our reports --

17:23:15 4 Q. Okay.

17:23:15 5 A. -- together.

17:23:16 6 Q. Getting back to the question: Do you have

17:23:18 7 any reason to doubt Dr. Borak's statement that

17:23:22 8 particles might contribute to the question of

17:23:22 9 coherency under the Bradford-Hill criteria?

17:23:25 10 MR. GORDON: Object to the form of the

17:23:26 11 question, incomplete hypothetical, also lack of

17:23:30 12 foundation.

17:23:30 13 A. As I say, I haven't read his report, so I

17:23:35 14 would have to read his report and study his report to

17:23:38 15 know exactly what he's saying. I don't -- I don't

16 know --

17:23:40 17 You're taking that sentence out of his

17:23:42 18 report, and you'll have to give me time to read the

17:23:45 19 report and to -- to -- to comment on it.

17:23:49 20 Q. Well let's look at the paragraph that he

17:23:51 21 discusses because it's three sentences long and I

22 don't think --

17:23:54 23 It's going to illuminate the issue.

17:24:05 24 (Exhibit 29 was marked for

17:24:07 25 identification.)

17:24:07 1 MR. GORDON: Page?

17:24:08 2 BY MR. SACCHET:

17:24:08 3 Q. If you could please turn to page 22, and

17:24:13 4 I'll read the isolated sentence and then we can turn

17:24:16 5 back to page 21 and read the preceding sentences.

17:24:21 6 A. Page 22?

17:24:22 7 Q. Yes.

17:24:24 8 A. These are references.

17:24:29 9 Q. You might be -- you might be looking at page

17:24:31 10 22 of the references as opposed to page 22 of the

17:24:34 11 report itself.

17:24:36 12 A. Oh, I'm sorry. This is --

17:24:38 13 I guess it's actually his CV. Okay. Sorry.

17:24:43 14 Q. At the top of page 22 it says, "However, as

17:24:46 15 discussed below, the particle count studies might

17:24:49 16 contribute to coherence." Do you see that?

17:24:51 17 A. Yes.

17:24:51 18 Q. Okay. I'm happy to read the preceding

17:24:54 19 sentence if that provides context for you. We can

17:24:57 20 look at the subsequent statements if that provides

17:25:00 21 context. What would be helpful to you?

17:25:06 22 A. "...might contribute to co" --

17:25:08 23 "...might contribute to coherence," what

17:25:25 24 does he mean by that? I'm not sure --

17:25:27 25 Oh.

17:25:27 1 Q. Okay. Well in this section of his report,
17:25:30 2 if you turn back a couple pages, on page 20 we see the
17:25:38 3 Samet opinion, correct, on the top of the page 20?

17:25:40 4 A. Right. Yes.

17:25:41 5 Q. And then paragraph 61 says "Strength of
17:25:43 6 Association," correct, as the --

17:25:46 7 A. Yeah.

17:25:46 8 Q. -- subject of that paragraph.

17:25:47 9 A. Uh-huh.

17:25:48 10 Q. Paragraph 65 has the consistency of the data
17:25:51 11 as the topic of that paragraph, and then the
17:25:55 12 paragraphs that follow that relate to consistency,
17:25:59 13 correct, because paragraph 70 is entitled "Coherence."

17:26:04 14 A. Oh, I see. So -- okay. So he's talking
17:26:06 15 about consistency. So I wasn't understanding what you
17:26:12 16 were saying for that.

17:26:16 17 Yeah, it says it "might contribute."

17:26:19 18 Q. You disagree with that statement.

17:26:22 19 A. It's a pretty vague statement, isn't it? I
17:26:25 20 don't know. It might. It might or it might not.

17:26:27 21 Q. Okay. Do you disagree with it?

17:26:29 22 Might it?

17:26:30 23 A. Might it? It might.

17:26:31 24 Q. Okay.

17:26:40 25 MR. SACCHET: Where are we at?

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17:26:42 1 THE VIDEOGRAPHER: We have 20 -- 21 minutes
17:26:45 2 remaining.
17:26:45 3 Q. With respect to making causal inferences,
17:26:51 4 mechanistic studies may be helpful; correct?
17:26:58 5 MR. GORDON: Object to the form of the
17:27:00 6 question.
17:27:02 7 A. What type of mechanistic studies are you --
17:27:06 8 are you indicating?
17:27:07 9 Q. So a study or a document that shows the
17:27:11 10 biological plausibility or the mechanism of infection
17:27:14 11 by which either a drug or a device or --
17:27:16 12 A. Okay.
17:27:17 13 Q. -- some entity might result in an increased
17:27:19 14 outcome at issue.
17:27:22 15 A. That can help, yes.
17:27:22 16 Q. That can help.
17:27:22 17 A. Yes.
17:27:23 18 Q. And in the event of two products, for
17:27:26 19 example, --
17:27:27 20 A. Uh-huh.
17:27:28 21 Q. -- would it be helpful if one particular
17:27:31 22 product, albeit a different product, had the same
17:27:35 23 mechanism of infection as a different product?
17:27:38 24 MR. GORDON: Object to the form of the
17:27:39 25 question.

17:27:46 1 A. I guess I would have to know exactly what
17:27:53 2 the -- what -- what was -- what -- what you're -- what
17:27:56 3 was involved in the two products and which was --

17:27:58 4 Q. So in the event that there is one product
17:28:00 5 like the Bair Hugger where Dr. Samet opines that one
17:28:03 6 of the causal mechanisms is the disruption of airflow
17:28:06 7 currents in the operating room that then deposit
17:28:08 8 bacteria on the surgical site, if that's the mechanism
17:28:12 9 of the Bair Hugger for the sake of an example --

17:28:13 10 Do you understand?

17:28:14 11 A. Okay.

17:28:14 12 Q. -- and if there were another product that
17:28:21 13 involved the same mechanism of infection of creating
17:28:26 14 currents of air in an operating room that caused
17:28:30 15 bacteria to be deposited at the surgical site, those
17:28:33 16 are the same mechanisms of infection; correct?

17:28:36 17 A. Uh-huh.

17:28:36 18 Q. But they're different products, for example.

17:28:38 19 A. Okay.

17:28:39 20 Q. Because the mechanism is the same, would
17:28:43 21 that contribute to coherency of drawing an inference
17:28:48 22 about causation?

17:28:49 23 MR. GORDON: Object to the form of the
17:28:51 24 question, incomplete hypothetical, assumes facts not
17:28:53 25 in evidence, lack of foundation.

17:28:55 1 A. Well it -- I mean I think if -- if --

17:29:00 2 It depends a lot, I think, on what the --

17:29:06 3 what the outcome is on -- on the -- the study that

17:29:09 4 you're --

17:29:10 5 Q. Same outcome. Let's say --

17:29:12 6 A. Infection?

17:29:13 7 Q. -- infection and that --

17:29:14 8 A. Deep infection?

17:29:15 9 Q. -- that's the one you've always been worried
17:29:17 10 about.

17:29:18 11 A. Okay. So if you're looking at a deep

17:29:20 12 infection, if that is the outcome that you're

17:29:22 13 measuring with these -- with these two different

17:29:24 14 devices, then -- then I think it would be helpful.

17:29:26 15 Q. What if it was SSI versus DJI?

17:29:30 16 MR. GORDON: Same objection.

17:29:32 17 A. It -- there it --

17:29:34 18 I mean when you start getting away from it,

17:29:36 19 then you really have to get into the details of what

17:29:39 20 it is that -- that you're -- what -- what it is you're

17:29:43 21 looking at and where the -- where the potential

17:29:46 22 differences could be.

17:29:46 23 Q. You need to look into those details with

17:29:49 24 respect to whether the SSI intervention measures have

17:29:52 25 an impact on deep joint infection; correct?

17:29:54 1 A. I was not separately studying the -- the SSI
17:29:58 2 and -- and DJI, yeah.

17:29:59 3 Q. Okay. But with respect to the two devices
17:30:02 4 that share the same exact mechanism of infection that
17:30:05 5 would both increase the risk of infection, that would
17:30:07 6 be helpful in determining whether there was biological
17:30:10 7 plausibility or coherency to whether there was an
17:30:12 8 increased risk of infection; correct?

17:30:14 9 MR. GORDON: Same objection.

17:30:17 10 A. It -- it -- it could be.

17:30:20 11 Q. Okay.

17:30:21 12 A. I don't know.

17:30:22 13 Q. Okay.

17:30:25 14 A. It depends on the details.

17:31:02 15 (Exhibit 30 was marked for
17:31:03 16 identification.)

17:31:03 17 BY MR. SACCHET:

17:31:06 18 Q. This is a document from the CDC; correct,
17:31:11 19 Dr. Holford?

17:31:12 20 A. It appears to be.

17:31:14 21 Q. Are you familiar with HICPAC?

17:31:17 22 A. I'm not familiar with it, no.

17:31:18 23 Q. Okay. If you could please turn to page 24
17:31:23 24 of that document, there is a title that says
17:31:38 25 "Nontuberculosis Mycobacterium Infections Associated

17:31:41 1 With Heater-Cooler Devices." Do you see that?

17:31:43 2 A. Yes.

17:31:44 3 Q. Okay. And heater-cooler devices are not the
17:31:47 4 same as Bair Huggers; correct?

17:31:49 5 A. I don't know what devices they're talking
17:31:51 6 about.

17:31:51 7 Q. Okay. The first sentence of text says, "Dr.
17:31:56 8 Perz reviewed points about Nontuberculosis
17:31:59 9 Mycobacterium and infections associated with
17:32:02 10 heater-cooler devices;" correct?

17:32:03 11 A. Yes.

17:32:04 12 Q. And this is talking about a device, whether
17:32:06 13 or not you know that it's the same as the Bair Hugger
17:32:08 14 or not; correct?

17:32:09 15 MR. GORDON: Object to the form of the
17:32:10 16 question, lack of foundation.

17:32:13 17 Q. Does -- does this say that there's a device
17:32:16 18 that they're discussing?

17:32:18 19 A. There is a device they're discussing.

17:32:20 20 Q. Okay.

17:32:20 21 A. I don't know --

17:32:21 22 I know nothing about it, --

17:32:22 23 Q. Yeah.

17:32:22 24 A. -- the device.

17:32:23 25 Q. I understand that.

17:32:24 1 On page 25 in the second paragraph --

17:32:28 2 A. Yeah.

17:32:29 3 Q. -- it says, "Two fans are present in the
17:32:30 4 heater-cooler."

17:32:31 5 A. Uh-huh.

17:32:32 6 Q. And it says, "This design is typical for
17:32:35 7 this class of device. One fan cools the device's
17:32:38 8 internal components, and another, larger fan draws air
17:32:41 9 into the machine." Correct?

17:32:42 10 A. Yes, that's what it says. Yeah.

17:32:44 11 Q. Do you know that the Bair Hugger draws air
17:32:46 12 into the machine so it warms patients through the hose
17:32:50 13 and into the blanket?

17:32:53 14 A. I -- I don't know very much about the de --

17:32:57 15 I -- I think that's what it does -- does. I
17:32:59 16 don't know a lot of detail about how the -- how the
17:33:01 17 Bair Hugger works.

17:33:02 18 Q. You don't know a lot of details about how
17:33:04 19 the Bair Hugger works?

17:33:05 20 A. No.

17:33:05 21 Q. Okay. On page 26 there are five bullets
17:33:14 22 listed there. Do you see them?

17:33:15 23 A. Yes.

17:33:15 24 Q. And the third one is, "Direct the exhaust
17:33:17 25 from the device away from the sterile field." Do you

17:33:20 1 see that?

17:33:20 2 A. Yes.

17:33:21 3 Q. Okay. And then on the subsequent page, page
17:33:25 4 27, in the last paragraph it says, "The heater-cooler
17:33:29 5 unit appears to be harmless from an infection
17:33:32 6 perspective, but the water overflow -- overflow bottle
17:33:34 7 is likely rarely, if ever, sanitized and is situated
17:33:38 8 in front of a fan. Nothing that blows air should be
17:33:40 9 in the operating theater, if possible." Do you see
17:33:42 10 that?

17:33:42 11 A. Yes.

17:33:44 12 Q. Do you know why they're concerned about
17:33:46 13 things blowing air in the operating room?

17:33:48 14 MR. GORDON: Object to the form of the
17:33:50 15 question, lack of foundation, it mischaracterizes the
17:33:52 16 evidence.

17:33:56 17 A. I mean I -- I --

17:33:58 18 This is the first I read this, I -- I've
17:34:00 19 seen this article. I -- it's -- it's -- it's really
17:34:05 20 not my -- my -- not my area.

17:34:08 21 Q. You've seen this article?

17:34:09 22 A. No, I have not seen it.

17:34:11 23 Q. You have not seen it.

17:34:12 24 A. That's what I said.

17:34:13 25 Q. Okay.

17:34:14 1 A. It -- I mean it -- it sort of co --
17:34:22 2 coincides with a lot of the concern of what we've been
17:34:25 3 talking about today.
17:34:27 4 Q. It does; correct?
17:34:28 5 A. It's really --
17:34:29 6 MR. GORDON: Same objections.
17:34:31 7 A. Well I think that was the bas -- basic --
17:34:34 8 the -- the purpose of the bubble study and whatnot, is
17:34:37 9 to consider --
10 Q. Yeah.
17:34:38 11 A. -- particles that were distributed in the
17:34:39 12 operating room.
17:34:41 13 Q. So this is describing a similar concern
17:34:44 14 based on the mechanism of infection; correct?
17:34:45 15 MR. GORDON: Same objection.
17:34:49 16 A. Well it doesn't say why. I mean I -- it
17:34:51 17 just --
17:34:51 18 Q. One of -- one of the mechanisms is that
17:34:53 19 blowing air in the operating room might create
17:34:56 20 convection currents that deposit bacteria at the
17:34:59 21 surgical site; correct?
17:35:00 22 MR. GORDON: Same objections.
17:35:02 23 A. I --
17:35:03 24 Q. According to Dr. Samet.
17:35:05 25 A. Well if it's Dr. Samet, I mean quote Dr.

17:35:09 1 Samet. It's not --

17:35:10 2 That's not my area. I mean we've already
17:35:14 3 established what his area is --

17:35:15 4 Q. Okay.

17:35:16 5 A. -- and this is an area that he feels
17:35:18 6 comfortable in and that -- and has -- has -- has done
17:35:22 7 work in, and this is not the area --

17:35:25 8 Q. You don't feel comfortable in this area.

17:35:27 9 A. It's not an area that I -- that I work
17:35:29 10 in, --

17:35:30 11 Q. Okay.

17:35:31 12 A. -- no.

17:35:31 13 Q. And so you're unclear about what the
17:35:33 14 mechanism of infection that is the issue with respect
17:35:35 15 to blowing air in the operating theater; is -- is
17:35:37 16 that -- is that your testimony?

17:35:39 17 MR. GORDON: Object to the form of the
17:35:40 18 question.

17:35:45 19 A. It's --

17:35:50 20 I mean the authors of this report are
17:35:53 21 obviously concerned about blowing -- you know, blowing
17:35:57 22 air over water that's -- water that's infected.

17:36:01 23 Q. Uh-huh.

17:36:01 24 A. I don't know enough about the mechanism of
17:36:04 25 the Bair Hugger --

17:36:05 1 Q. Yeah.

17:36:05 2 A. -- to know exactly what is --

17:36:08 3 Is there a pool of water in the Bair Hugger
17:36:11 4 that it -- that it's blowing air over?

17:36:13 5 Q. Okay.

17:36:13 6 A. I don't know.

17:36:14 7 Q. So you've opined about whether one can draw
17:36:18 8 a causal inference as to whether the Bair Hugger
17:36:19 9 increases the risk of infection, but you don't
17:36:22 10 understand the ways in which the Bair Hugger might in
17:36:25 11 fact result in an increase in infection.

17:36:27 12 MR. GORDON: Object to the form of the
17:36:28 13 question, misstates his testimony.

17:36:30 14 A. I think -- I think that's not -- not an
17:36:33 15 accurate description of what -- what I've -- what I've
17:36:37 16 been saying. I was looking at the -- the evidence for
17:36:41 17 a causal -- a causal association --

17:36:44 18 Q. Uh-huh.

17:36:45 19 A. -- and does -- that has in -- that has
17:36:47 20 basically involved looking at what the -- the design
17:36:54 21 and the estimates of effect that were known to me
17:36:58 22 at the -- at the time that I did that -- did that
17:37:01 23 analysis.

17:37:01 24 Q. And that's it.

17:37:02 25 A. And that's basically what I was drawing my

17:37:05 1 con -- conclusions are about -- about causal
17:37:09 2 inference.

17:37:09 3 Q. Okay.

17:37:09 4 A. It was basically the strength --

17:37:11 5 Q. Uh-huh.

17:37:13 6 A. -- in terms of not only the magnitude of the
17:37:14 7 effect, but in terms of the design that was used
17:37:19 8 and -- to -- to find those -- those associations and
17:37:24 9 whether that is -- the strength of that evidence is --
17:37:26 10 was enough to demonstrate a causal -- a causal
17:37:31 11 association.

17:37:32 12 Q. Do you agree with the statement from The
17:37:33 13 Reference Manual on Statistics that "In the end,
17:37:36 14 deciding whether associations are causal typically is
17:37:39 15 not a matter of statistics alone, but also rests on
17:37:42 16 scientific judgment?"

17:37:43 17 A. Yes.

17:37:43 18 Q. You've only considered the statistical
17:37:46 19 aspects; correct?

17:37:48 20 A. Well I tried to consider the -- the other
17:37:52 21 aspects of -- of the -- of the study as well.

17:37:55 22 Q. You said you have no expertise and have not
17:37:58 23 delved into the literature as to those additional
17:38:01 24 topics; correct?

17:38:04 25 A. Of the associated -- of things related

17:38:10 1 specifically to these devices. I was primarily
17:38:13 2 concentrating on the studies that had been done on the
17:38:17 3 epidemiology.

17:38:18 4 Q. And those studies are the McGovern study and
17:38:21 5 the Augustine study, which are the only two
17:38:25 6 epidemiologic studies on the risk of infection from
17:38:27 7 the Bair Hugger to deep joint infection; correct?

17:38:31 8 A. For the Bair -- for the Bair Hugger effect,
17:38:35 9 the Bair Hugger/Hot Dog comparison, those were the --
17:38:42 10 basically the studies that I was comparing.

17:38:44 11 MR. SACCHET: Okay. We're going to look at
17:38:45 12 one more document. Maybe two, but --

17:38:54 13 (Exhibit 31 was marked for
17:38:55 14 identification.)

17:38:57 15 BY MR. SACCHET:

17:38:58 16 Q. This is another document from the CDC;
17:39:05 17 correct?

17:39:05 18 MR. GORDON: Objection, lack of foundation.

17:39:09 19 THE REPORTER: We have eight minutes left.

17:39:11 20 Q. Does the title page of this document,
17:39:15 21 professor, show the CDC's logo on it?

17:39:16 22 A. Yes.

17:39:17 23 Q. Okay. And if you could please turn to page
17:39:29 24 12 of the document, it states "FDA Device Updates:
17:39:36 25 Flexible Endoscopes and Heater Coolers;" correct?

17:39:39 1 A. Yes.

17:39:39 2 Q. Okay. If you could turn to page 15 of the
17:39:42 3 document, there are a number of bullet points;
17:39:47 4 correct?

17:39:47 5 A. Yes.

17:39:48 6 Q. And the fourth one down says, "The
17:39:50 7 orientation of the vent(s) on the devices may or may
17:39:53 8 not direct the fan exhaust toward the patient or the
17:39:55 9 sterile field. The exhaust from cooling fans may also
17:39:58 10 play a role in the airflow within the OR, possibly
17:40:02 11 facilitating movement of the aerosolized NTM into the
17:40:06 12 sterile field." Do you see that?

17:40:07 13 A. Yes.

17:40:07 14 Q. Is that the same mechanism of infection that
17:40:09 15 Dr. Samet described in his report?

17:40:11 16 MR. GORDON: Object to the form of the
17:40:12 17 question, lack of foundation, assumes facts not
17:40:15 18 evidence, mischaracterizes the testimony.

17:40:19 19 A. I -- I don't recall the detail of how --
17:40:24 20 what Dr. Samet's description was on -- on -- on the --
17:40:29 21 on the -- on devices used.

17:40:30 22 Q. One of the issues in this litigation that
17:40:33 23 was discussed in the McGovern study, which you are
17:40:35 24 aware of, is that the Bair Hugger might generate
17:40:37 25 convection currents that results in increased

17:40:40 1 particles over the surgical site; correct?

17:40:41 2 A. Yes. Yes.

17:40:42 3 Q. This bullet says that "The exhaust from
17:40:44 4 cooling fans may also play a role in the airflow
17:40:47 5 within the OR, possibly facilitating movement of the
17:40:50 6 aerosolized NTM into the sterile field." Do you see
17:40:53 7 that?

17:40:55 8 MR. GORDON: Objection, asked and answered.

17:40:56 9 Q. You've seen it.

17:40:57 10 Does that describe a similar mechanism of
17:41:03 11 moving particles or bacteria to the sterile field?

17:41:06 12 MR. GORDON: Well wait, wait, wait. You
17:41:06 13 started out with talking about convection currents,
17:41:09 14 now you're changing gears. What -- what are you
17:41:11 15 asking him?

17:41:12 16 Q. I'm asking: One of the mechanisms of
17:41:13 17 infection described in the McGovern study is the
17:41:16 18 movement of particles from air currents generated by
17:41:20 19 the Bair Hugger; correct?

17:41:20 20 MR. GORDON: Well before you said convection
17:41:22 21 currents, not --

17:41:23 22 MR. SACCHET: Okay.

17:41:23 23 MR. GORDON: You say you're changing that
17:41:26 24 now?

17:41:27 25 MR. SACCHET: I am.

17:41:27 1 MR. GORDON: Okay.

17:41:28 2 MR. SACCHET: Yes.

17:41:28 3 Q. That's correct.

17:41:28 4 A. Okay.

17:41:30 5 Q. And this bullet, which is from the CDC that
17:41:34 6 we established, says that "The exhaust from cooling
17:41:36 7 fans may also play a role in the airflow within the
17:41:39 8 OR, possibly facilitating the movement of the
17:41:43 9 aerosolized NTM into the sterile field;" correct?

17:41:47 10 A. It possibly is.

11 MR. GORDON: Objection, asked and answered.

12 Q. Possibly?

13 MR. GORDON: You read it right.

14 A. Yes.

17:41:48 15 Q. Okay.

17:41:49 16 MR. GORDON: Are you asking him if he -- if
17:41:50 17 he has any basis for --

18 MR. SACCHET: No, I'm not, Corey.

17:41:52 19 MR. GORDON: -- saying anything --
17:41:52 20 commenting on that?

17:41:53 21 MR. SACCHET: Please don't use the rest of
17:41:56 22 my time. I'm not going to engage --

17:41:56 23 MR. GORDON: Well I want -- I want to get an
17:41:56 24 objection. I thought you were just, once again,
17:41:58 25 reading the same sentence. If you're asking him to

17:42:00 1 comment on it, I object on the grounds of lack of
17:42:03 2 foundation.

17:42:03 3 Q. Does this describe a similar mechanism of
17:42:06 4 infection as noted by McGovern et al in the study that
17:42:08 5 you have reviewed?

17:42:09 6 MR. GORDON: Object to the form of the
17:42:10 7 question, also lack of foundation, also
17:42:13 8 mischaracterizes the evidence.

17:42:16 9 A. I'm not sure it --

17:42:23 10 It's un -- it's unclear. I mean just that
17:42:25 11 sentence, I can't figure out -- I -- I -- I'm not --
17:42:30 12 unclear as to whether -- how this relates to what
17:42:32 13 McGovern is saying.

17:42:34 14 Q. Did you try to shore up your
17:42:35 15 misunderstanding or questions about that statement?

17:42:38 16 A. Well I mean you just -- you just showed me
17:42:39 17 this, --

17:42:40 18 Q. Okay. So you -- you didn't investigate --

17:42:42 19 A. -- so how could I --

17:42:43 20 Q. You didn't investigate this.

17:42:44 21 A. Not when --

17:42:45 22 No. I mean you asked me this question
17:42:46 23 about --

17:42:47 24 Q. You didn't know about it.

17:42:49 25 A. -- a minute before. I didn't know about

17:42:50 1 this report, no.

17:42:51 2 MR. SACCHET: Okay. I'm going to show you
17:42:53 3 one other document.

17:43:06 4 (Exhibit 32 was marked for
17:43:08 5 identification.)

17:43:08 6 BY MR. SACCHET:

17:43:08 7 Q. This is a document bearing the Bates number
17:43:11 8 3MBH0001 -- 1336; correct?

17:43:15 9 A. Yes.

17:43:15 10 Q. Have you seen it before?

17:43:16 11 A. No.

17:43:22 12 Q. The top line says "CONFIDENTIAL - NOT FOR
17:43:25 13 EXTERNAL DISTRIBUTION;" correct?

17:43:26 14 A. Yes.

17:43:27 15 Q. And then the bolded typeface says "Arizant
17:43:30 16 forced-air warming and SSI prevention: Talking points
17:43:32 17 for sales;" correct?

17:43:33 18 A. Yes.

17:43:33 19 Q. And it says "Our position." The first line
17:43:36 20 is, "There is no evidence that forced-air warming
17:43:39 21 (FAW) increases risk of surgical site infections
17:43:42 22 (SSIs)...;" correct?

17:43:43 23 A. That's what it says.

17:43:44 24 Q. And there's a comment right next to it;
17:43:46 25 correct?

17:43:46 1 A. Yes.

17:43:47 2 Q. And it says, "Actually, there is evidence
17:43:49 3 that FAW use increases risk." Do you see that?

17:43:53 4 A. Yes.

17:43:54 5 Q. Do you know who wrote that statement?

17:43:57 6 A. No, I don't.

17:43:57 7 Q. Do you know whether that statement was
17:44:00 8 written by a 3M employee?

17:44:01 9 MR. GORDON: Object to the form of the
17:44:03 10 question, lack of foundation.

17:44:04 11 A. I've never seen this document before, so I
17:44:07 12 have no idea.

17:44:08 13 Q. Are you surprised that this statement was
17:44:10 14 made in a document that's confidential regarding
17:44:13 15 Arizant talking points on SSI prevention?

17:44:16 16 MR. GORDON: Object to the form of the
17:44:17 17 question, lack of foundation, misstates --
17:44:19 18 mischaracterizes the evidence.

17:44:22 19 A. I don't --

17:44:23 20 I mean I know basically nothing about this
17:44:28 21 document.

17:44:29 22 Q. You've never seen it before.

17:44:30 23 A. I've never seen it before.

17:44:31 24 Q. Okay. Did you look at any documents that
17:44:35 25 had a 3M Bates number on it, like this in the bottom

17:44:39 1 right-hand corner, as part of your review?

17:44:43 2 A. Any documents that had --

17:44:45 3 Q. That had a Bates number bearing the prefix

17:44:47 4 3MBH.

17:44:50 5 A. I don't recall. I -- al -- although I don't

17:44:53 6 know --

17:44:53 7 I didn't look carefully at that Bates number

17:44:56 8 on all of the documents. I don't recall that.

17:45:00 9 Q. Were any internal 3M documents provided to

17:45:04 10 you as part of your review of the evidence in this

17:45:06 11 case?

17:45:07 12 A. No.

17:45:08 13 Q. Did you meet with any people from 3M with

17:45:12 14 respect to preparing your report?

17:45:13 15 A. No, I did not.

17:45:14 16 MR. SACCHET: Okay. I will reserve the rest

17:45:18 17 of my time.

17:45:23 18 THE REPORTER: Off the record, please.

17:45:40 19 (Discussion off the record.)

17:45:40 20 MR. GORDON: We'll read -- we'll read and

17:45:42 21 sign.

17:45:44 22 MR. SACCHET: I'd like to make one note.

17:45:50 23 THE REPORTER: Let's go back on the record.

17:45:53 24 MR. SACCHET: To the extent that Dr. Holford

17:45:56 25 has noted in his report that he reviewed documents

17:45:58 1 provided by 3M with respect to the use of the Bair
17:46:02 2 Hugger at particular hospitals in the NHS and that
17:46:06 3 those documents were not cited in his report, I'm
17:46:08 4 leaving the deposition open.

17:46:09 5 THE REPORTER: Off the record, please.

17:46:16 6 (Deposition concluded.)

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1 C E R T I F I C A T E

2 I, Richard G. Stirewalt, hereby certify that
3 I am qualified as a verbatim shorthand reporter, that
4 I took in stenographic shorthand the deposition of
5 THEODORE R. HOLFORD at the time and place aforesaid,
6 and that the foregoing transcript is a true and
7 correct, full and complete transcription of said
8 shorthand notes, to the best of my ability.

9 Dated at Deerwood, Minnesota, this 23rd day
10 of July, 2017.

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17 RICHARD G. STIREWALT

18 Registered Professional Reporter

19 Notary Public

20

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22

23

24

25

1 C E R T I F I C A T E

2 I, THEODORE R. HOLFORD, hereby certify that
 3 I have carefully read the foregoing transcript, and
 4 that the same is a true and complete, full and correct
 5 transcription of my deposition, except:

6 PAGE/LINE CHANGE REASON

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16

17 THEODORE R. HOLFORD

18 Deponent

19

20 Signed and sworn to before me this ____ day of
 21 August, 2017.

22

23

24 Notary Public

25